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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

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: 001-37507

IMMUNITYBIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**43-1979754**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3530 John Hopkins Court San Diego , California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (844) 696-5235

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 $0.0001 per share	**IBRX**	**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 þ No ☐

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

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

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

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

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

The number of shares of the Registrant's common stock outstanding as of November 8, 2024 was 696,831,296 (excluding 163,800 shares held by a majority owned subsidiary of ours which are treated as treasury shares for accounting purposes).

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Defined Terms

Unless expressly indicated or the context required otherwise, the terms “ImmunityBio,” “the company,” “we,” “us,” and “our” in this Quarterly Report refer to ImmunityBio, Inc., a Delaware corporation, and, where appropriate, its subsidiaries. We have also used several other terms in this Quarterly Report, the unaudited condensed consolidated financial statements and accompanying notes included herein, most of which are defined below:

Term	Definition
2015 Plan	ImmunityBio, Inc. 2015 Equity Incentive Plan
3M IPC	3M Innovative Properties Company
3PL Agent	logistics agent
AAHI	Access to Advanced Health Institute
ACA	Affordable Care Act
Altor	Altor BioScience, LLC
America Invents Act	Leahy-Smith America Invents Act
Amyris	Amyris, Inc.
ANKTIVA®	Proprietary name for N-803 (formerly ALT-803), our novel IL-15 agonist complex (nogapendekin alfa inbakicept-pmln) currently approved for use in the United States with BCG for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer with *carcinoma in situ* with or without papillary tumors, and currently in clinical development for other indications.
Annual Report	Annual Report on Form 10-K for the year ended December 31, 2023
Approved product	ANKTIVA
ASC	Accounting Standards Codification
ASU	Accounting Standards Update
Athenex	Athenex, Inc.
ATM	“at-the-market” sales agreement
ATRA	American Taxpayer Relief Act of 2012
BCG	Bacillus Calmette-Guérin
Beike	Shenzhen Beike Biotechnology Co. Ltd.
BLA	Biologics License Application
BPCIA	Biologics Price Competition and Innovation Act of 2009
Brink	Brink Biologics, Inc.
Cambridge	Cambridge Equities, LP
CCPA	California Consumer Privacy Act of 2018
CEO	chief executive officer
CFO	chief financial officer
cGMP	current Good Manufacturing Practice
China	when used in connection with the RIPA, People’s Republic of China, Hong Kong and any territories controlled by the People’s Republic of China
CIS	carcinoma in situ
Clinic	Immuno-Oncology Clinic, Inc.
Closing Date	when used in connection with the RIPA, December 29, 2023
CMC	Chemistry, Manufacturing and Controls
CMO	contract manufacturing organization
CMS	Centers for Medicare & Medicaid Services
Code	Internal Revenue Code of 1986, as amended

Term	Definition
CPRA	California Privacy Rights Act
CRL	complete response letter
CRO	contract research organization
CVR	contingent value right
DGCL	Delaware General Corporation Law
Duley Road	Duley Road, LLC
Dunkirk Facility	a leasehold interest in a cGMP ISO Class 5 pharmaceutical manufacturing space in western New York
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
Exchange Act	Securities Exchange Act of 1934, as amended
Exyte	Exyte U.S., Inc.
FASB	Financial Accounting Standards Board
FCA	False Claims Act
FCPA	U.S. Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FIFO	First In First Out inventory method
FSMC	Fort Schuyler Management Corporation, a not-for-profit corporation affiliated with the State of New York
FTO	freedom-to-operate
FVO	fair value option
GBM	glioblastoma multiforme
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GTP	Good Tissue Practice
hAd5	human adenovirus serotype 5
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984
HCPCS	Healthcare Common Procedure Coding System, a set of standardized codes used in the U.S. to describe specific medical procedures, services, equipment, medications, and supplies.
HCW	HCW Biologics, Inc.
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act
HIV	human immunodeficiency virus
IgDraSol	IgDraSol, Inc., a subsidiary of the company
IND	investigational new drug
Infinity	Infinity SA LLC, as purchaser agent for affiliates of Oberland
IPR&D	In-process research and development
IRA	Inflation Reduction Act of 2022
IRS	Internal Revenue Service
J-code	a part of the HCPCS used to designate non-oral medications and other medical devices
LMIC	low- and middle-income countries

Term	Definition
MAA	Marketing Authorization Application
mAbs	monoclonal antibodies
MHRA	Medicines and Healthcare products Regulatory Agency
Nant Capital	Nant Capital, LLC
NantBio	NantBio, Inc.
NantCell	NantCell, Inc., a subsidiary of the company
NANTibody	Immunotherapy NANTibody, LLC, a subsidiary of the company
NantKwest	NantKwest, Inc.
NantPharma	NantPharma, LLC
NantWorks	NantWorks, LLC, a related-party
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NCSC	NantCancerStemCell, LLC
NDA	New Drug Application
NEO	named executive officer
NK	natural killer
NMIBC	non-muscle invasive bladder cancer
NOL	net operating loss
NSCLC	non-small cell lung cancer
Oberland	Oberland Capital Management LLC and its affiliates (including Purchasers as defined in the RIPA)
OFAC	U.S. Treasury Department's Office of Foreign Assets Control
PHI	Protected Health Information
PMA	premarket approval
QMSR	Quality Management System Regulation
QSR	Quality System Regulation
Quarterly Report	Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2024
QUILT	QUantitative Integrated Lifelong Trial
RDO	registered direct offering
REMS	Risk Evaluation and Mitigation Strategy
RIPA	Revenue Interest Purchase Agreement
RSU	restricted stock unit
SAFE	Simple Agreement for Future Equity
Sarbanes-Oxley	Sarbanes-Oxley Act of 2002
saRNA	self-amplifying RNA
SARS-CoV-2	novel strain of the coronavirus (COVID-19)
SEC	U.S. Securities and Exchange Commission
Section 404	Section 404 of the Sarbanes-Oxley Act of 2002
Securities Act	Securities Act of 1933, as amended
Sorrento	Sorrento Therapeutics, Inc.
SPOA	Stock Purchase and Option Agreement
TAA	tumor-associated antigen
TCJA	Tax Cuts and Jobs Act of 2017

Term	Definition
TF Platform	tissue factor-based fusion discovery platform
Term SOFR	Term Secured Overnight Financing Rate
Test Date	when used in connection with the RIPA, December 31, 2029
TGF-β	transforming growth factor beta
TLR	toll-like receptor
U.S. GAAP	accounting principles generally accepted in the United States of America
UK	United Kingdom
UK GDPR	UK Data Protection Act of 2018
USPTO	U.S. Patent and Trademark Office
VBC Holdings	VBC Holdings, LLC, a subsidiary of the company
VIE	variable interest entity
VivaBioCell	VivaBioCell, S.p.A., a wholly-owned subsidiary of VBC Holdings

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,966	$ 265,453
Marketable securities	18,401	1,009
Accounts receivable, net	4,175	—
Inventories	1,958	—
Due from related parties	729	2,019
Prepaid expenses and other current assets (including amounts with related parties)	25,921	25,603
Total current assets	163,150	294,084
Marketable securities, noncurrent	—	891
Property, plant and equipment, net	139,285	146,082
Goodwill and intangible assets, net	16,479	17,093
Convertible note receivable	7,067	6,879
Operating lease right-of-use assets, net (including amounts with related parties)	34,946	36,543
Other assets (including amounts with related parties)	3,643	2,880
Total assets	$ 364,570	$ 504,452
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,945	$ 9,195
Accrued expenses and other liabilities	43,596	42,708
Due to related parties	386	1,136
Operating lease liabilities (including amounts with related parties)	7,033	5,244
Total current liabilities	60,960	58,283
Related-party nonconvertible note, net of discount (Note 11)	111,143	104,586
Related-party convertible notes and accrued interest, net of discount (Note 11)	587,975	576,951
Revenue interest liability (Note 10)	273,657	155,415
Operating lease liabilities, less current portion (including amounts with related parties)	36,761	39,942
Derivative liabilities (Note 10) and (Note 11)	19,223	35,333
Warrant liabilities	18,308	118,770
Other liabilities	705	1,109
Total liabilities	1,108,732	1,090,389

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets (Continued)
(in thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Common stock, $ 0.0001 par value; 1,350,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 696,831,296 and 670,867,344 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively; excluding treasury stock, 163,800 shares outstanding as of September 30, 2024 and December 31, 2023	$ 70	$ 67
Additional paid-in capital	2,570,765	2,374,620
Accumulated deficit	(3,316,086)	(2,961,684)
Accumulated other comprehensive income	103	10
Total ImmunityBio stockholders' deficit	(745,148)	(586,987)
Noncontrolling interests	986	1,050
Total stockholders' deficit	(744,162)	(585,937)
Total liabilities and stockholders' deficit	$ 364,570	$ 504,452

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue				
Product revenue, net	$ 5,954	$ —	$ 6,944	$ —
Other revenues	152	82	249	483
Total revenue	6,106	82	7,193	483
Operating costs and expenses				
Cost of product revenue	—	—	—	—
Research and development (including amounts with related parties)	50,443	48,402	154,923	180,834
Selling, general and administrative (including amounts with related parties)	35,916	31,816	127,052	96,510
Total operating costs and expenses	86,359	80,218	281,975	277,344
Loss from operations	(80,253)	(80,136)	(274,782)	(276,861)
Other income (expense), net				
Interest and investment income, net	1,798	35	6,788	647
Change in fair value of warrant liabilities	31,324	14,265	10,222	31,800
Interest expense (including amounts with related parties)	(29,322)	(35,021)	(88,599)	(97,072)
Interest expense related to revenue interest liability	(10,925)	—	(28,154)	—
Change in fair value of derivative liabilities	1,614	—	20,084	—
Change in fair value of related-party convertible note	—	7,517	—	749
Loss on equity method investment	—	(1,255)	—	(7,549)
Other income (expense), net (including amounts with related parties)	12	(1,047)	(25)	(2,152)
Total other expense, net	(5,499)	(15,506)	(79,684)	(73,577)
Loss before income taxes and noncontrolling interests	(85,752)	(95,642)	(354,466)	(350,438)
Income tax expense	—	—	—	—
Net loss	(85,752)	(95,642)	(354,466)	(350,438)
Net loss attributable to noncontrolling interests, net of tax	(23)	(60)	(64)	(634)
Net loss attributable to ImmunityBio common stockholders	$ (85,729)	$ (95,582)	$ (354,402)	$ (349,804)
Net loss per ImmunityBio common share – basic	$ (0.12)	$ (0.19)	$ (0.52)	$ (0.77)
Net loss per ImmunityBio common share – diluted	$ (0.14)	$ (0.19)	$ (0.53)	$ (0.77)
Weighted-average number of common shares used in computing net loss per share – basic	695,895	498,375	685,261	454,994
Weighted-average number of common shares used in computing net loss per share – diluted	697,961	498,375	688,939	454,994

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (85,752)	$ (95,642)	$ (354,466)	$ (350,438)
Other comprehensive income (loss), net of income taxes:				
Net unrealized gains on available-for-sale securities	39	48	31	46
Reclassification of net realized losses (gains) on available-for-sale securities included in net loss	10	(18)	55	(12)
Foreign currency translation adjustments	62	(18)	7	(245)
Change in fair value of convertible note related to instrument-specific credit risk	—	820	—	820
Total other comprehensive income	111	832	93	609
Comprehensive loss	(85,641)	(94,810)	(354,373)	(349,829)
Less: Comprehensive loss attributable to noncontrolling interests	23	60	64	634
Comprehensive loss attributable to ImmunityBio common stockholders	$ (85,618)	$ (94,750)	$ (354,309)	$ (349,195)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Deficit
(in thousands, except share amounts)
(Unaudited)

	Nine Months Ended September 30, 2024							
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Balance as of December 31, 2023	670,867,344	$ 67	$ 2,374,620	$ (2,961,684)	$ 10	$ (586,987)	$ 1,050	$ (585,937)
Stock-based compensation expense	—	—	8,266	—	—	8,266	—	8,266
Vesting of RSUs	2,969,156	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(1,117,737)	—	(3,867)	—	—	(3,867)	—	(3,867)
Exercise of warrants	4,284,648	1	24,701	—	—	24,702	—	24,702
Other comprehensive (loss) income, net of tax	—	—	—	—	(17)	(17)	—	(17)
Net loss	—	—	—	(134,109)	—	(134,109)	(21)	(134,130)
Balance as of March 31, 2024	677,003,411	68	2,403,720	(3,095,793)	(7)	(692,012)	1,029	(690,983)
Issuance of common stock "at-the-market" offering, net of commissions and offering costs of $ 660	427,368	—	3,625	—	—	3,625	—	3,625
Stock-based compensation expense	—	—	9,639	—	—	9,639	—	9,639
Exercise of stock options	146,199	—	429	—	—	429	—	429
Vesting of RSUs	222,578	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(83,220)	—	(496)	—	—	(496)	—	(496)
Exercise of warrants	13,217,843	1	107,438	—	—	107,439	—	107,439
Exercise of Oberland stock option, net of commissions of $ 150	858,990	—	7,554	—	—	7,554	—	7,554
Other comprehensive (loss) income, net of tax	—	—	—	—	(1)	(1)	—	(1)
Net loss	—	—	—	(134,564)	—	(134,564)	(20)	(134,584)
Balance as of June 30, 2024	691,793,169	69	2,531,909	(3,230,357)	(8)	(698,387)	1,009	(697,378)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Deficit (Continued)
(in thousands, except share amounts)
(Unaudited)

	Nine Months Ended September 30, 2024							
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Stock-based compensation expense	—	$ —	$ 7,489	$ —	$ —	$ 7,489	$ —	$ 7,489
Exercise of stock options	162,760	—	286	—	—	286	—	286
Vesting of RSUs	214,875	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(79,757)	—	(299)	—	—	(299)	—	(299)
Exercise of warrants	4,740,249	1	31,380	—	—	31,381	—	31,381
Other comprehensive (loss) income, net of tax	—	—	—	—	111	111	—	111
Net loss	—	—	—	(85,729)	—	(85,729)	(23)	(85,752)
Balance as of September 30, 2024	696,831,296	$ 70	2,570,765 $	(3,316,086) $	103	$ (745,148)	$ 986	$ (744,162)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Deficit (Continued)
(in thousands, except share amounts)
(Unaudited)

	Nine Months Ended September 30, 2023							
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Balance as of December 31, 2022	421,569,115	$ 42	$ 1,930,936	$ (2,378,488)	$ 183	$ (447,327)	$ (2,493)	$ (449,820)
Issuance of shares in an RDO, net of discount and offering costs of $ 2,046 and value ascribed to associated warrants	14,072,615	1	24,255	—	—	24,256	—	24,256
Stock-based compensation expense	—	—	10,878	—	—	10,878	—	10,878
Exercise of stock options	81,037	—	126	—	—	126	—	126
Vesting of RSUs	313,975	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(113,638)	—	(357)	—	—	(357)	—	(357)
Other comprehensive (loss) income, net of tax	—	—	—	—	(216)	(216)	—	(216)
Net loss	—	—	—	(116,343)	—	(116,343)	(240)	(116,583)
Balance as of March 31, 2023	435,923,104	43	1,965,838	(2,494,831)	(33)	(528,983)	(2,733)	(531,716)
Issuance of common stock "at-the-market" offering, net of commissions and offering costs of $ 313	4,605,323	1	13,615	—	—	13,616	—	13,616
Stock-based compensation expense	—	—	11,062	—	—	11,062	—	11,062
Exercise of stock options	26,583	—	135	—	—	135	—	135
Vesting of RSUs	140,269	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(21,382)	—	(60)	—	—	(60)	—	(60)
Other comprehensive (loss) income, net of tax	—	—	—	—	(7)	(7)	—	(7)
Net loss	—	—	—	(137,879)	—	(137,879)	(334)	(138,213)
Balance as of June 30, 2023	440,673,897	44	1,990,590	(2,632,710)	(40)	(642,116)	(3,067)	(645,183)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Deficit (Continued)
(in thousands, except share amounts)
(Unaudited)

	Nine Months Ended September 30, 2023							
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Issuance of common stock in exchange for notes payable	209,291,936	$ 21	$ 269,966	—	—	$ 269,987	—	$ 269,987
Increase in fair value of embedded conversion feature from debt modification with entities under common control	—	—	31,179	—	—	31,179	—	31,179
Issuance of shares in an RDO, net of discount and offering costs of $ 1,489 and value ascribed to associated warrants	14,569,296	2	12,673	—	—	12,675	—	12,675
Issuance of common stock under "at-the market" offering net of commissions and offering costs of $ 160	1,000,000	—	2,490	—	—	2,490	—	2,490
Stock-based compensation expense	—	—	14,449	—	—	14,449	—	14,449
Exercise of stock options	75,616	—	32	—	—	32	—	32
Vesting of RSUs	3,035,845	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(943,550)	—	(1,464)	—	—	(1,464)	—	(1,464)
Change in ownership interest in a joint venture due to legal settlement (Note 8)	—	—	(4,199)	—	—	(4,199)	4,199	—
Other comprehensive (loss) income, net of tax	—	—	—	—	832	832	—	832
Net loss	—	—	—	(95,582)	—	(95,582)	(60)	(95,642)
Balance as of September 30, 2023	667,703,040	$ 67	2,315,716 $	(2,728,292) $	792	$ (411,717)	$ 1,072	$ (410,645)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (354,466)	$ (350,438)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense related to the revenue interest liability	27,715	—
Stock-based compensation expense	25,394	36,389
Change in fair value of derivative liabilities	(20,084)	—
Amortization of related-party notes discounts	17,580	35,278
Depreciation and amortization	13,416	13,948
Change in fair value of warrant liabilities	(10,222)	(31,800)
Non-cash lease expense related to operating lease right-of-use assets	4,141	4,786
Accretion of discounts on marketable debt securities	(1,465)	(16)
Non-cash interest items, net (including amounts with related parties)	(187)	8,988
Unrealized losses on equity securities	520	851
Change in fair value of convertible note	—	(749)
Transaction costs allocated to warrant liabilities	—	2,010
Other	146	(459)
Changes in operating assets and liabilities:		
Accounts receivable	(4,175)	—
Inventories	(1,958)	—
Prepaid expenses and other current assets	370	9,463
Other assets	(74)	1,385
Accounts payable	47	(3,599)
Accrued expenses and other liabilities	606	26,205
Related parties	540	(1,299)
Operating lease liabilities	(3,936)	(2,429)
Net cash used in operating activities	(306,092)	(251,486)
Investing activities:		
Purchases of marketable debt securities, available-for-sale	(134,129)	(10,192)
Proceeds from maturities of marketable debt securities, available-for-sale	97,552	—
Proceeds from sales of marketable debt securities	21,021	102
Purchases of property, plant and equipment	(4,777)	(22,629)
Acquisition of a business, net of transaction costs	(1,000)	—
Cash paid for other investments	(747)	—
Net cash used in investing activities	(22,080)	(32,719)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows (Continued)
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Financing activities:		
Proceeds from the RIPA, net of issuance costs	$ 96,956	$ —
Proceeds from exercises of warrants	73,281	—
Proceeds from exercise of Oberland stock option, net of commissions	4,850	—
Net share settlement for RSUs vesting	(4,662)	(1,881)
Proceeds from equity offerings, net of discounts and issuance costs	3,625	100,747
Proceeds from exercises of stock options	715	293
Principal payments of finance leases	(64)	(57)
Proceeds from issuance of related-party promissory notes, net of issuance costs paid	—	258,700
Net cash provided by financing activities	174,701	357,802
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	(16)	(265)
Net change in cash and cash equivalents, and restricted cash	(153,487)	73,332
Cash and cash equivalents, and restricted cash, beginning of period	265,787	104,965
Cash and cash equivalents, and restricted cash, end of period	$ 112,300	$ 178,297

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

ImmunityBio, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows (Continued)
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Reconciliation of cash and cash equivalents, and restricted cash, end of period:		
Cash and cash equivalents	$ 111,966	$ 177,963
Restricted cash	334	334
Cash and cash equivalents, and restricted cash, end of period	$ 112,300	$ 178,297
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ 71,452	$ 32,902
Income taxes	$ 15	$ —
Supplemental disclosure of non-cash activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 2,576	$ —
Property and equipment purchases included in accounts payable, accrued expenses and due to related parties	$ 1,363	$ 10,902
Unrealized gains on marketable debt securities, net	$ 86	$ 34
Conversion of note payable into common stock	$ —	$ 269,987
Initial measurement of warrants issued in connection with RDOs accounted for as liabilities	$ —	$ 49,534
Increase in fair value of embedded conversion feature from debt modification	$ —	$ 31,179
Change in ownership interest in a joint venture due to legal settlement	$ —	$ 4,199
Unpaid offering costs included in accounts payable and accrued expenses	$ —	$ 186

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

ImmunityBio, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements

1. Description of Business

In these notes to unaudited condensed consolidated financial statements, the terms “ImmunityBio,” “the company,” “we,” “us,” and “our” refer to ImmunityBio, Inc. and its subsidiaries.

Our Business

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The company’s range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

Our platforms and their associated product and product candidates are designed to attack cancer and infectious pathogens by activating both the innate immune system, including—NK cells, dendritic cells, and macrophages, as well as—the adaptive immune system comprising—B and T cells,—in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally-infected. Our ultimate goal is to overcome the limitations of current treatments, such as checkpoint inhibitors, and/or reduce the need for standard high-dose chemotherapy in cancer by employing this coordinated approach to establish “immunological memory” that confers long-term benefit for the patient.

Our proprietary platforms for the development of biologic product candidates include: (i) antibody-cytokine fusion proteins, (ii) DNA, RNA, and recombinant protein vaccines, and (iii) cell therapies. As of September 2024, our platforms have generated nine first-in-human therapeutic agents (including one FDA-approved agent) that are currently or planned to be studied in clinical trials in liquid and solid tumors. Specifically, our clinical focus includes bladder, lung, and colorectal cancers and GBM, which are among the most frequent and lethal cancer types, and where there are high failure rates for existing standards of care or no available effective treatment.

Our lead biologic product ANKTIVA is a novel first-in-class IL-15 agonist antibody-cytokine fusion protein. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors (the “approved product”). We began commercial distribution of our approved product in May 2024.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and pursuant to the rules and regulations of the SEC. The unaudited condensed consolidated financial statements reflect all adjustments which are, in the opinion of management, necessary for a fair presentation of our financial position and results of operations. Certain items in the prior year’s consolidated financial statements have been reclassified to conform to the current presentation. These reclassifications had no effect on the reported results of operations. The unaudited condensed consolidated financial statements do not include all information and notes required by U.S. GAAP for annual reports and therefore should be read in conjunction with our consolidated financial statements and the notes thereto contained in our Annual Report filed with the SEC on March 19, 2024. These interim financials are not necessarily indicative of results expected for the full fiscal year.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of the company, its wholly-owned subsidiaries, and a VIE for which the company is the primary beneficiary. Any material intercompany transactions and balances have been eliminated upon consolidation. For consolidated entities where we have less than 100% of ownership, we record *net loss attributable to noncontrolling interests, net of tax,* on the condensed consolidated statement of operations equal to the percentage of the ownership interest retained in such entities by the respective noncontrolling parties.

We assess whether we are the primary beneficiary of a VIE at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE.

If the entity is within the scope of the variable interest model and meets the definition of a VIE, we consider whether we must consolidate the VIE or provide additional disclosures regarding our involvement with the VIE. If we determine that we are the primary beneficiary of the VIE, we will consolidate the VIE. This analysis is performed at the initial investment in the entity or upon any reconsideration event.

For entities we hold as an equity investment that are not consolidated under the VIE model, we consider whether our investment constitutes a controlling financial interest in the entity and therefore should be considered for consolidation under the voting interest model.

Liquidity

As of September 30, 2024, the company had an accumulated deficit of $ 3.3 billion. We also had negative cash flows from operations of $ 306.1 million during the nine months ended September 30, 2024. The company will likely need additional capital to commercialize our approved product, and to further fund the development of, and to seek regulatory approvals for, our other product candidates.

The condensed consolidated financial statements have been prepared assuming the company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of the uncertainty of our ability to continue as a going concern. As a result of continuing anticipated operating cash outflows as we commercialize our approved product and accelerate our development efforts, we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support. However, we believe our existing cash and cash equivalents, and investments in marketable securities; sales of our approved product; capital to be raised through equity offerings, including but not limited to, the offering, issuance and sale by us of our common stock under the ATM, of which we had $ 296.5 million available for future issuance as of September 30, 2024; and our potential ability to borrow from affiliated entities will be sufficient to fund our operations through at least the next 12 months following the issuance date of the consolidated financial statements based primarily upon our Founder, Executive Chairman and Global Chief Scientific and Medical Officer's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt.

In addition to funds from the future sales of our approved product, which we expect to take time to establish, we may also seek to sell additional equity, through one or more follow-on offerings, or in separate financings, or obtain incremental subordinated debt in compliance with our existing revenue interest liability. However, we may not be able to secure such external financing in a timely manner or on favorable terms. Without significant sales of our approved product or additional funds, we may choose to delay or reduce our operating or investment expenditures. Further, because of the risk and uncertainties associated with the commercialization of our approved product and our other product candidates, we may need additional funds to meet our needs sooner than planned.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make certain 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 revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to the valuation of equity-based awards, deferred income taxes and related valuation allowances, preclinical and clinical trial accruals, impairment assessments, CVR measurement and assessments, the measurement of right-of-use assets and lease liabilities, useful lives of long-lived assets, loss contingencies, fair value calculation of warrants, stock options, derivative liabilities, convertible promissory notes, fair value measurements, revenue interest liability, revenue recognition, accruals for research and development activities, and the assessment of our ability to fund our operations for at least the next 12 months from the date of issuance of these condensed consolidated financial statements. We base our estimates on historical experience and on various other market-specific and relevant assumptions that we believe to be reasonable under the circumstances. Estimates are assessed each period and updated to reflect current information and anticipated future events, and accordingly, actual results may ultimately differ materially from those estimates.

Significant Accounting Policies

Our significant accounting policies are described in Note 2, *Summary of Significant Accounting Policies,* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of our Annual Report filed with the SEC on March 19, 2024, except as updated herein or as it relates to revenue recognition, cost of product revenue, accounts receivable, inventory, warrants, convertible notes, debt, revenue interest liability, derivative liabilities and the adoption of new accounting standards during the nine months ended September 30, 2024. Management does not believe that any recently issued, but not yet effective accounting pronouncements, if currently adopted, would have a material effect on the company's consolidated financial statements.

Revenues

Product Sales

After FDA approval in April 2024, the company began recognizing revenue from the sale of ANKTIVA in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606). Revenue from product sales is recorded at the net sales price ("transaction price"), which includes an estimate of variable consideration. An estimate of variable consideration is based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, chargebacks, discounts and other deductions and returns established at the time of sale.

Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, our experience, current contractual and statutory requirements, specific known market events and trends. These reductions to gross sales reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in future periods vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known. As we gain more experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the ANKTIVA product launch.

The company entered into a third-party logistics agreement to engage a 3PL Agent to distribute the company's products to its customers. The 3PL Agent provides services to the company that include storage, shipping and distribution, processing product returns, as well as customer service, order to cash, and logistics support. The company's customers are currently limited to pharmaceutical specialty distributors (each a "Customer") pursuant to a drop-ship arrangement whereby the 3PL Agent will ship products to end customers of such Customers. Our Customers subsequently sell ANKTIVA to hospitals, medical facilities, physician practices, pharmacies and government agencies. Revenue from product sales is recognized when our performance obligations are satisfied, which is upon delivery to the end customer.

Other Revenues

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

License Agreements with Third Parties

The company has nonexclusive license agreements with a limited number of pharmaceutical and biotechnology companies that grant them the right to use our cell lines and intellectual property for non-clinical use. These agreements generally include upfront fees and annual research license fees for such use, as well as commercial license fees for sales of the licensee products developed or manufactured using our intellectual property and cell lines.

Under our license agreements with customers, we typically promise to provide a license to use certain cell lines and related patents, the related know-how, and future research and development data that affect the license. We have concluded that these promises represent a single performance obligation due to the highly interrelated nature of the promises. We provide the cell lines and know-how immediately upon entering into the contracts. Research and development data are provided throughout the term of the contract when and if available. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

Our license agreements may include non-refundable upfront payments, event-based milestone payments, sales-based royalty payments, or some combination of these. The event-based milestone payments represent variable consideration, and we use the most likely amount method to estimate this variable consideration. Given the high degree of uncertainty around the achievement of these milestones, we do not recognize revenue from these milestone payments until the uncertainty associated with these payments is resolved. We currently estimate variable consideration related to milestone payments to be zero and, as such, no revenue has been recognized for milestone payments. We recognize revenue from sales-based royalty payments when or as sales occur. On a quarterly basis, we re-evaluate our estimate of milestone variable consideration to determine whether any amount should be included in the transaction price and recorded in revenue prospectively.

Other Product and Services Revenue

We sell our proprietary GMP-in-a-Box bioreactors and related consumables to affiliated companies and third parties. The arrangements typically include delivery of bioreactors, consumables, and providing installation service and perpetual software licenses for using the equipment. We recognize revenue when customers obtain control and can benefit from the promised goods or services, generally upon installation of the bioreactors, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. Upfront payments and fees are recorded as deferred revenue upon receipt and recognized as revenue when we satisfy our performance obligations under these arrangements.

Grant Revenue

Grant revenue is typically paid for reimbursable costs incurred over the duration of the associated research project or clinical trial and is recognized either when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due or when cash is received, depending on the certainty of payment and other factors specific to each grant.

Cost of Product Revenue

Cost of product revenue consists primarily of third-party manufacturing costs, distribution, and overhead costs related to sales of approved product subsequent to receiving regulatory approval. Cost of product revenue may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense* , on the condensed consolidated statement of operations in the period incurred and therefore are not reflected in cost of product revenue.

Accounts Receivable, Net

Accounts receivable is recorded net of allowances for prompt payment discounts, returns, and credit losses. The company estimates an allowance for credit losses by considering factors such as credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. As of September 30, 2024, the credit profile for the company's counterparty was deemed to be in good standing, and as such an allowance for credit losses was not recorded.

Inventory

We began to capitalize inventory costs associated with ANKTIVA during the three months ended June 30, 2024 after receiving FDA approval in April 2024 when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined using the FIFO method. Inventory costs include the cost of materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation.

The company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first identified. Such impairment charges, if they occur, are recorded in *cost of product revenue*, on the condensed consolidated statement of operations.

Because FDA approval was recently received and the company capitalized its first inventory as of June 30, 2024. As of September 30, 2024, no reserve has been established. The company will continue to monitor if a reserve is needed at each reporting period.

Warrants

The company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480), and ASC Topic 815, *Derivatives and Hedging* (ASC 815). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as a component of *additional paid-in capital,* on the condensed consolidated statement of stockholders' deficit at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and on each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recorded as a non-cash gain or loss in *other income (expense), net*, on the condensed consolidated statement of operations. The fair value of the warrants was estimated using the Black-Scholes option pricing model.

Fair Value Option Election

The company accounted for a convertible note issued on March 31, 2023 under the FVO election of ASC Topic 825, *Financial Instruments* (ASC 825) until it was amended and restated on December 29, 2023. Prior to its extinguishment on December 29, 2023, the convertible note was a debt host financial instrument containing embedded features wherein the entire financial instrument was initially measured at its issuance-date fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date.

Changes in the estimated fair value of this convertible note were recorded in *other (expense) income, net,* on the condensed consolidated statement of operations, except that changes in estimated fair value caused by changes in the instrument-specific credit risk are included in *other comprehensive income (loss)*. In accordance with FASB ASC Topic 470-50, *Debt – Modifications and Extinguishments* (ASC 470-50), when the convertible note was extinguished on December 29, 2023, the cumulative amount previously recorded in *other comprehensive (loss) income* resulting from changes in the instrument-specific credit risk were reclassified and reported in current earnings on the condensed consolidated statement of operations. See Note 11, *Related-Party Debt*, for more information.

Debt Modification and Extinguishment

The company evaluates amendments to its debt instruments in accordance with ASC 470-50. This evaluation includes comparing (1) if applicable, the net present value of future cash flows of the amended debt to that of the original debt and (2) the change in fair value of an embedded conversion feature to that of the carrying amount of the debt immediately prior to amendment to determine, in each case, if a change greater than 10% occurred. In instances where the net present value of future cash flows or the fair value of an embedded conversion feature, if any, changed more than 10%, the company applies extinguishment accounting. In instances where the net present value of future cash flows and the fair value of an embedded conversion feature, if any, changed less than 10%, the company accounts for the amendment to the debt as a debt modification. Gains and losses on debt amendments that are considered extinguishments are recognized in current earnings or in additional paid-in capital if the transactions are with entities under common control. Debt amendments that are considered debt modifications are accounted for prospectively through yield adjustments, based on the revised terms. The increase in fair value of the embedded conversion feature from the debt modification was accounted for as an increase in debt discount with a corresponding increase in additional paid-in capital. Legal fees and other costs incurred with third parties that are directly related to debt modifications are expensed as incurred. Amounts paid by the company to the lenders, are reflected as additional debt discount and amortized as an adjustment of interest expense over remaining term of modified debt using the effective interest method.

Revenue Interest Liability

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain Revenue Interests (as defined in the RIPA) from us for a gross purchase price of $ 200.0 million paid on closing and acquired additional Revenue Interests from us for a gross purchase price of $ 100.0 million paid on May 13, 2024. Under the RIPA, Oberland has the right to receive quarterly payments from us based on, among other things, a certain percentage of our worldwide net sales, excluding those in China, during such quarter. The RIPA is considered a sale of future revenues and is accounted for as a liability net of a debt discount comprised of deferred issuance costs, the fair value of a freestanding option agreement related to the SPOA, and the fair value of embedded derivatives requiring bifurcation on the consolidated balance sheet. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. Interest expense is recognized over the estimated term on the consolidated statement of operations. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of actual and forecasted net sales. The company evaluates the interest rate quarterly based on actual and forecasted net sales utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales will materially impact the revenue interest liability, interest expense, and the time period for repayment.

Derivative Liabilities

Embedded derivatives that are required to be bifurcated from the underlying debt instrument that do not meet the derivative scope exception and equity classification criteria are accounted for and valued as separate financial instruments. The terms of an embedded derivative related to a contingent exercisable prepayment feature of a convertible note have been evaluated and deemed to require bifurcation. This embedded derivative was initially measured at fair value and will be remeasured to fair value at each reporting date until the derivative is settled.

In addition, the RIPA contains certain features that meet the definition of being an embedded derivative requiring bifurcation as a separate compound financial instrument apart from the RIPA. In May 2024, Oberland acquired additional Revenue Interests for a gross purchase price of $ 100.0 million, and the company recorded an incremental portion of the fair value of the derivative liability as of the funding date of $ 6.2 million as a debt discount, which is being amortized in *interest expense,* on the condensed consolidated statement of operations along with the initial debt discount over the expected term of the debt using the effective interest rate method. The fair value of the derivative liability is subject to remeasurement at each reporting period, with changes in fair value recognized in *other income (expense), net*, on the condensed consolidated statement of operations.

Basic and Diluted Net Loss per Share of Common Stock

Basic net loss per share is calculated by dividing the net loss attributable to ImmunityBio common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share is computed by dividing net loss attributable to ImmunityBio common stockholders by the weighted-average number of common shares, including the number of additional shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

The following table reflects the calculation of basic and diluted loss per common share (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Net loss per ImmunityBio common share – basic				
Numerator:				
Net loss attributable to ImmunityBio common stockholders	$ (85,729)	$ (95,582)	$ (354,402)	$ (349,804)
Denominator:				
Weighted-average number of common shares outstanding – basic	695,895	498,375	685,261	454,994
Net loss per ImmunityBio common share – basic	$ (0.12)	$ (0.19)	$ (0.52)	$ (0.77)
Net loss per ImmunityBio common share – diluted				
Numerator:				
Net loss	$ (85,752)	$ (95,642)	$ (354,466)	$ (350,438)
Less: Net loss attributable to noncontrolling interests, net of tax	(23)	(60)	(64)	(634)
Add: Increase (decrease) in fair value of warrant liabilities	(14,505)	—	(10,553)	—
Numerator for net loss per ImmunityBio common share – diluted	$ (100,234)	$ (95,582)	$ (364,955)	$ (349,804)
Denominator:				
Weighted-average number of common shares outstanding – basic	695,895	498,375	685,261	454,994
Add: Dilutive effect of assumed exercise of “in-the-money” third-party warrants	2,066	—	3,679	—
Denominator for net loss per ImmunityBio common share – diluted	697,961	498,375	688,939	454,994
Net loss per ImmunityBio common share – diluted	$ (0.14)	$ (0.19)	$ (0.53)	$ (0.77)

Potentially dilutive securities, whose effect would have been antidilutive, were excluded from the computation of diluted net loss per share. The following table details the number of shares of common stock underlying those securities that were excluded from the computation of weighted-average number of common shares outstanding – diluted (shares in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Related-party convertible notes	162,472	116,517	162,472	116,517
Outstanding third-party warrants	9,091	37,733	9,091	37,733
Outstanding stock options	15,451	9,862	15,451	9,862
Outstanding RSUs	6,559	8,604	6,559	8,604
Outstanding related-party warrants	1,638	1,638	1,638	1,638
Total	195,211	174,353	195,211	174,353

The potentially dilutive securities shown in the table above exclude an option to purchase up to approximately $ 5.0 million of the company's common stock pursuant to the SPOA entered in connection with the RIPA, as the exercise price cannot be determined until the date of exercise.

Recent Accounting Pronouncements

Application of New or Revised Accounting Standards – Adopted

In June 2022, the FASB, issued ASU 2022-03 , *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* , which clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This ASU also clarifies that an entity cannot, as a separate unit of account, recognize and measure a contractual sale restriction and introduces certain disclosure requirements for equity securities subject to such restrictions. We adopted this ASU on January 1, 2024 on a prospective basis with no impact on our condensed consolidated financial statements.

In March 2023, the FASB issued ASU 2023-01, *Leases-Common Control Arrangements (Topic 842).* This ASU provides updated guidance for accounting for leasehold improvements associated with common control leases. We adopted this ASU on January 1, 2024 on a prospective basis with no impact on our condensed consolidated financial statements.

Application of New or Revised Accounting Standards – Not Yet Adopted

In August 2023, the FASB issued ASU 2023-05, *Business Combinations-Joint Venture Formations (Subtopic 805-60): Recognition and Initial Measurement*, which requires a joint venture to initially measure all contributions received upon its formation at fair value. This ASU is applicable to joint venture entities with a formation date on or after January 1, 2025 on a prospective basis. We will apply this guidance prospectively in future reporting periods after the guidance is effective to any future arrangements meeting the definition of a joint venture.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* , which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. We are currently evaluating the impact of this standard on our disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to improve its income tax disclosure requirements. Under the ASU, entities must annually (1) disclose specific categories in the rate reconciliation, (2) provide additional information for reconciling items that meet a quantitative threshold, and (3) disclose more detailed information about income taxes paid, including by jurisdiction; pretax income (or loss) from continuing operations; and income tax expense (or benefit). The ASU is effective for fiscal years beginning after December 15, 2024, and interim periods beginning after December 15, 2025, with early adoption permitted. We are currently evaluating the impact of this standard on our disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), and the SEC during the nine months ended September 30, 2024 did not, or are not expected to, have a material effect on our condensed consolidated financial statements.

3. Revenues

As discussed in Note 2, *Summary of Significant Accounting Policies*, revenues are recognized in accordance with ASC 606. The following table presents our disaggregated revenue for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Product revenue, net	$ 5,954	$ —	$ 6,944	$ —
Other revenues	152	82	249	483
Total revenue	$ 6,106	$ 82	$ 7,193	$ 483

Product Revenue, Net

During the three and nine months ended September 30, 2024, our only source of product revenue has been from U.S. sales of ANKTIVA, which we began shipping to customers in May 2024.

As of September 30, 2024, approximately $ 1.0 million of gross-to-net accruals have been recorded as a reduction to revenue, of which approximately $ 0.5 million is a reduction of *accounts receivable, net* and approximately $ 0.5 million is presented in *accrued expenses and other current liabilities* on the condensed consolidated balance sheet.

Other Revenues

During the three and nine months ended September 30, 2024, our primary sources of other revenues were bioreactors and related consumable product sales.

4. Financial Statement Details

Prepaid Expenses and Other Current Assets

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

	September 30, 2024 (Unaudited)	December 31, 2023
Prepaid research and development costs	$ 9,050	$ 7,847
Prepaid services	6,256	5,869
Prepaid software license fees	2,841	2,100
Insurance premium financing asset	2,163	1,475
Prepaid rent	1,463	1,113
Prepaid equipment maintenance	1,338	1,183
Prepaid insurance	1,150	2,242
ERP system implementation cost	293	1,087
Insurance claims receivable	—	1,149
Other	1,367	1,538
Prepaid expenses and other current assets	$ 25,921	$ 25,603

Inventories

Inventories consist of the following (in thousands):

	September 30, 2024 (Unaudited)	December 31, 2023
Raw materials	$ —	$ —
Work-in-progress	1,958	—
Finished goods	—	—
Inventories	$ 1,958	$ —

Inventory is stated at the lower of cost or net realizable value and consists of raw materials, work-in-progress and finished goods. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. Inventory that is used for clinical development purposes is expensed in *research and development expense,* on the condensed consolidated statement of operations when consumed.

Cost of product revenue consists primarily of third-party manufacturing costs, distribution, and overhead costs related to sales of approved product subsequent to receiving regulatory approval. Cost of product revenue may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the condensed consolidated statement of operations in the period incurred and therefore are not reflected in cost of product revenue.

The work-in-progress materials consists of bulk drug substance and drug product, which have a multi-year shelf life. When the bulk drug substance is manufactured into ANKTIVA drug product, those goods have a shelf life of two years from the date of manufacture. During September 2024, the shelf life of ANKTIVA drug product was extended to three years. The work-in-progress drug product gets converted to finished goods at the time of labeling. Our expectation is to sell finished goods at least twelve months prior to expiration. Due to our long manufacturing lead time, it was necessary to build up inventory in support of ANKTIVA forecasted sales. As a result of being in the early stages of the ANKTIVA product launch, the company is continuing to evaluate the length of its operating cycle.

On a quarterly basis, the company analyzes its inventory levels for excess quantities and obsolescence (expiration), taking into account factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf life. As of September 30, 2024, we determined that a reserve related to ANKTIVA inventory for excess quantities and obsolescence was not required. In addition, since the FDA approval of ANKTIVA the company has not recorded any inventory write downs.

Property, Plant and Equipment, Net

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

	September 30, 2024 (Unaudited)	December 31, 2023
Leasehold improvements	$ 72,570	$ 72,552
Equipment	73,588	69,915
Construction in progress	85,716	84,436
Furniture & fixtures	1,896	1,889
Software	1,660	1,666
Gross property, plant and equipment	235,430	230,458
Less: Accumulated depreciation and amortization	96,145	84,376
Property, plant and equipment, net	$ 139,285	$ 146,082

During the three months ended September 30, 2024 and 2023, depreciation expense related to property, plant and equipment totaled $ 3.9 million and $ 4.1 million, respectively, and $ 11.9 million and $ 12.4 million during the nine months ended September 30, 2024 and 2023, respectively.

Goodwill and Intangible Assets, Net

The gross carrying amounts, accumulated amortization and impairment of goodwill and intangible assets, net are as follows at the dates indicated (in thousands):

	September 30, 2024 (Unaudited)				
	Weighted-Average Life (in years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment	Net Carrying Amount
Definite-lived: Favorable leasehold rights	7.4	$ 20,398	$ (5,355)	$ —	$ 15,043
Indefinite-lived:					
Goodwill (1)		910	—	—	910
IPR&D		526	—	—	526
Total indefinite-lived assets		1,436	—	—	1,436
Goodwill and intangible assets, net		$ 21,834	$ (5,355)	$ —	$ 16,479

(1) In September 2024, we entered into an asset purchase agreement with an unrelated party pursuant to which the company acquired the rights to hire its workforce and purchase certain office equipment in exchange for consideration of $ 1.0 million, net of transaction costs. The transaction was accounted for as a business combination. The fair value of the acquired identifiable net assets was $ 0.1 million. We recognized the remaining $ 0.9 million as goodwill subject to impairment assessment in subsequent reporting periods.

	December 31, 2023				
	Weighted-Average Life (in years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment	Net Carrying Amount
Definite-lived: Favorable leasehold rights	8.1	$ 20,398	$ (3,825)	$ —	$ 16,573
Indefinite-lived: IPR&D		1,406	—	(886)	520
Goodwill and intangible assets, net		$ 21,804	$ (3,825)	$ (886)	$ 17,093

We recorded amortization expense of our definite-lived intangible assets totaling $ 0.5 million during the three months ended September 30, 2024 and 2023 and $ 1.5 million during the nine months ended September 30, 2024 and 2023 in *research and development expense*, on the condensed consolidated statements of operations.

Future amortization expense associated with our definite-lived intangible assets, net is as follows (in thousands):

Years ending December 31:	Definite-lived Intangible Assets (Unaudited)
2024 (excluding the nine months ended September 30, 2024)	$ 510
2025	2,040
2026	2,040
2027	2,040
2028	2,040
2029	2,040
Thereafter	4,333
Total	$ 15,043

Accrued Expenses and Other Liabilities

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

	September 30, 2024 (Unaudited)	December 31, 2023
Accrued professional and service fees	$ 11,973	$ 9,829
Accrued bonus	9,722	11,350
Accrued research and development costs	7,708	7,700
Accrued compensation	6,969	6,241
Accrued preclinical and clinical trial costs	2,963	4,218
Financing obligation – current portion	2,163	1,475
Accrued construction costs	686	1,179
Other	1,412	716
Accrued expenses and other liabilities	$ 43,596	$ 42,708

Interest and Investment Income, Net

Interest and investment income, net consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Investment accretion income, net	$ 1,675	$ —	$ 5,732	$ —
Interest income	638	610	1,631	1,486
Unrealized losses from equity securities	(505)	(593)	(520)	(851)
Net realized (losses) gains on investments	(10)	18	(55)	12
Interest and investment income, net	$ 1,798	$ 35	$ 6,788	$ 647

Interest income includes interest from marketable securities, convertible notes receivable, other assets, and on bank deposits.

Interest Expense

Interest expense consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Interest expense on related-party notes payable	$ 23,123	$ 23,548	$ 70,987	$ 61,750
Amortization of related-party notes discounts	6,199	11,454	17,580	35,278
Other interest expense	—	19	32	44
Interest expense (including amounts with related parties)	$ 29,322	$ 35,021	$ 88,599	$ 97,072

5. Financial Instruments

Investments in Marketable Debt Securities

As of September 30, 2024, the weighted-average remaining contractual life, amortized cost, gross unrealized gains, gross unrealized losses and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	September 30, 2024 (Unaudited)				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
U.S. Treasury securities	0.1	$ 17,999	$ 5	$ —	$ 18,004

As of September 30, 2024, no marketable debt securities were in an unrealized loss position.

As of December 31, 2023, the weighted-average remaining contractual life, amortized cost, gross unrealized gains, gross unrealized losses and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	December 31, 2023				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
Foreign bonds	0.8	$ 54	$ —	$ —	$ 54
Mutual funds		40	—	(1)	39
Current portion		94	—	(1)	93
Noncurrent:					
Foreign bonds	3.3	939	—	(48)	891
Total		$ 1,033	$ —	$ (49)	$ 984

Accumulated unrealized losses on marketable debt securities that have been in a continuous loss position for less than 12 months and more than 12 months as of December 31, 2023 were as follows (in thousands):

	December 31, 2023			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Mutual funds	$ 39	$ (1)	$ —	$ —
Foreign bonds	891	(48)	—	—
Total	$ 930	$ (49)	$ —	$ —

Investments in Marketable Equity Securities

As of September 30, 2024 and December 31, 2023, we held investments in marketable equity securities with readily determinable fair values of $ 0.4 million and $ 0.9 million, respectively. Unrealized losses recorded on these securities totaled $ 0.5 million and $ 0.6 million during the three months ended September 30, 2024 and 2023, respectively, and losses of $ 0.5 million and $ 0.9 million during the nine months ended September 30, 2024 and 2023, respectively, in *interest and investment income, net*, on the condensed consolidated statements of operations.

Investment in Other Equity Security

In August 2024, the company entered into a SAFE with an unrelated party in exchange for the right to acquire certain shares of the investee. Upon the closing of equity financing by the investee prior to the termination of the SAFE, the SAFE will convert into preferred shares. We elected to apply the measurement alternative under ASC Topic 321, *Investments—Equity Securities*, pursuant to which we measure our investment in the SAFE at cost, less impairment. We recorded an investment in the SAFE of $ 0.7 million in *other assets*, on the condensed consolidated balance sheet as of September 30, 2024. We evaluate this investment for any indications of impairment in value on a quarterly basis.

6. Fair Value Measurements

Fair value is defined as an exit price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. We use a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires us to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value.

The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets at the measurement date. Since valuations are based on quoted prices that are readily and regularly available in an active market, the valuation of these products does not entail a significant degree of judgment. Our Level 1 assets consist of bank deposits, money market funds, and marketable equity securities.
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities. Our Level 2 assets consist of corporate debt securities including commercial paper, government-sponsored securities and corporate bonds, as well as foreign municipal securities.
- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

We utilize a third-party pricing service to assist in obtaining fair value pricing for our investments in marketable debt securities. Inputs are documented in accordance with the fair value disclosure hierarchy. The fair values of financial instruments other than marketable securities and cash and cash equivalents are determined through a combination of management estimates and third-party valuations.

Recurring Valuations

Financial assets and liabilities measured at fair value on a recurring basis are summarized below (in thousands):

	Fair Value Measurements at September 30, 2024 (Unaudited)			
	Total	Level 1	Level 2	Level 3
Assets at Fair Value:				
Current:				
Cash and cash equivalents	$ 111,966	$ 111,966	$ —	$ —
Equity securities	397	397	—	—
U.S. Treasury securities	18,004	18,004	—	—
Total assets measured at fair value	$ 130,367	$ 130,367	$ —	$ —
Liabilities at Fair Value:				
Current:				
Contingent consideration	$ (20)	$ —	$ —	$ (20)
Noncurrent:				
Stock option purchase liability (Note 10)	(290)	—	—	(290)
Derivative liabilities (Note 10 and Note 11)	(19,223)	—	—	(19,223)
Warrant liabilities (Note 13)	(18,308)	—	—	(18,308)
Total liabilities measured at fair value	$ (37,841)	$ —	$ —	$ (37,841)

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets at Fair Value:				
Current:				
Cash and cash equivalents	$ 265,453	$ 265,453	$ —	$ —
Equity securities	916	916	—	—
Foreign bonds	54	—	54	—
Mutual funds	39	39	—	—
Noncurrent:				
Foreign bonds	891	—	891	—
Total assets measured at fair value	$ 267,353	$ 266,408	$ 945	$ —
Liabilities at Fair Value:				
Current:				
Contingent consideration	$ (20)	$ —	$ —	$ (20)
Noncurrent:				
Stock option purchase liability (Note 10)	(819)	—	—	(819)
Derivative liabilities (Note 10 and Note 11)	(35,333)	—	—	(35,333)
Warrant liabilities (Note 13)	(118,770)	—	—	(118,770)
Total liabilities measured at fair value	$ (154,942)	$ —	$ —	$ (154,942)

7. Collaboration and License Agreements and Acquisition

Collaboration Agreement

Amyris Joint Venture

In 2021, ImmunityBio and Amyris entered into a 50:50 joint venture arrangement and formed a new limited liability company to conduct the business of the joint venture. The purpose of the joint venture is to accelerate commercialization of a next-generation COVID-19 vaccine utilizing an RNA vaccine-platform. As part of the limited liability agreement, Amyris contributed $ 1.0 million in cash and rights to its license agreement with AAHI for an RNA platform for the field of COVID-19. ImmunityBio contributed $ 1.0 million in cash and priority access to its manufacturing capacity for the joint venture product. Both parties agreed to enter into a separate manufacturing and supply agreement and a sublicense agreement following the execution of the joint venture agreement.

The joint venture agreement stipulates the initial terms for equal representation in the management of the newly-formed joint venture. The joint venture is managed by a board of directors consisting of four directors: two appointed by the company and two appointed by Amyris. Both parties agreed to make additional capital contributions in cash, in proportion to their respective interests, as determined by the board of directors of the joint venture.

We considered the joint venture entity as a VIE and determined that we are not the primary beneficiary of the VIE. We account for our investment in the joint venture using the equity method of accounting. During the three and nine months ended September 30, 2023, we recorded our 50 % share of the net loss from the joint venture totaling $ 1.3 million and $ 7.5 million in *other income (expense), net,* on the condensed consolidated statement of operations. Such losses incurred were attributable to expenses incurred by us on behalf of the joint venture. We are not obligated to fund the joint venture's potential future losses. In August 2023, Amyris announced that it filed for Chapter 11 bankruptcy protection. The Amyris bankruptcy case remains ongoing, and there can be no assurance that we will receive any recovery on account of our claims against Amyris, including for Amyris' portion of expenses incurred by the joint venture. As of September 30, 2024, the carrying amount of our equity investment in the joint venture was zero .

License Agreements

3M IPC and AAHI License Agreement

We have licensed rights to 3M-052, a synthetic TLR7/8 agonist, 3M-052 formulations and related technology from 3M IPC and its affiliates and AAHI. In 2021 we obtained nonexclusive rights in the field of SARS-CoV-2 and in June 2022 we modified those rights and expanded the scope of the license to include (1) SARS-CoV-2 and other infectious diseases including malaria, HIV, tuberculosis, hookworm and varicella zoster on an exclusive basis in countries other than LMIC, and (2) oncology applications, when used in combination with our proprietary technology and/or IL-15 agonists. In consideration for the license, we agreed to make certain periodic license payments, including $ 2.25 million each year through June 2025. We have also agreed to make payments upon the achievement of certain regulatory milestone events and tiered royalties ranging from the low to high single-digits as a percentage of net sales. Beginning in April 2026, the annual minimum licensing payment is $ 1.0 million, which can be credited against any royalty payments due under this agreement.

During the three months ended September 30, 2024 and 2023, we expensed $ 0.6 million, in *research and development expense* , on the condensed consolidated statements of operations. During the nine months ended September 30, 2024 and 2023, we expensed $ 1.7 million and $ 1.5 million, respectively, in *research and development expense* , on the condensed consolidated statements of operations.

AAHI License Agreements

In May 2021, we entered into two license agreements with AAHI pursuant to which we received a license to certain patents and know-how relating to AAHI's (i) adjuvant formulations for the treatment, prevention and/or diagnosis of SARS-CoV-2 (the AAHI Adjuvant Formulation License Agreement) and (ii) RNA vaccine platform as further described below (the AAHI RNA License Agreement). Under both agreements, we were obligated to pay one-time, non-creditable, non-refundable upfront cash payments totaling $ 2.0 million. In addition, under the AAHI Adjuvant Formulation License Agreement we owe milestone payments to a total of up to $ 2.5 million based on the achievement of certain development and regulatory milestones for the first licensed product and royalties on annual net sales of licensed products on a country-by-country and product-by-product basis of a low-single digit percentage, subject to certain royalty-reduction provisions. During the nine months ended September 30, 2024 and 2023, no milestone fees were incurred.

In September 2021, we amended and restated the AAHI RNA License Agreement, pursuant to which AAHI granted us an exclusive, worldwide, sublicensable license to AAHI's rights to an RNA vaccine platform for the development and commercialization of certain therapeutic, diagnostic or prophylactic products for the prevention, treatment or diagnosis of any indication, other than those subject to pre-existing third-party license grants, including, without limitation, SARS-CoV-2. Pursuant to the terms of the amended and restated AAHI RNA License Agreement, we made a one-time, non-creditable, non-refundable, upfront payment to AAHI of $ 1.5 million and a license maintenance fee of $ 3.0 million in June 2022. The company is required to pay license maintenance fees to AAHI of $ 5.5 million annually from 2023 through 2030. The company may terminate the restated agreement without cause by paying AAHI a $ 10.0 million one-time early termination fee. In addition, the milestone payments to AAHI based on the achievement of certain development and regulatory milestones for the first licensed product were amended to a total of up to $ 4.0 million. We are required to pay royalties on annual net sales of licensed products on a country-by-country and product-by-product basis of a low- to mid-single digit percentage. As of September 30, 2024, a $ 1.8 million payable to AAHI in connection with the annual license maintenance fee was recorded in *accrued expenses and other liabilities* , on the condensed consolidated balance sheet. As of December 31, 2023, $ 2.3 million was recorded in *prepaid expenses and other current assets* , on the condensed consolidated balance sheet in connection with the AAHI annual license maintenance fee. During the three months ended September 30, 2024 and 2023, we expensed $ 1.4 million, and during the nine months ended September 30, 2024 and 2023, we expensed $ 4.2 million and $ 3.1 million, respectively, in *research and development expense,* on the condensed consolidated statements of operations.

In connection with the license agreements, in May 2021 we also entered into a sponsored research agreement with AAHI pursuant to which we will fund continued research of at least $ 2.0 million per year, payable in four equal quarterly installments each year until May 2024, or such year of earlier termination. As of September 30, 2024 and December 31, 2023, we recorded a $ 2.0 million and a $ 1.2 million payable to AAHI in connection with the sponsored research agreement, respectively, in *accrued expenses and other liabilities* , on the condensed consolidated balance sheets. During the three months ended September 30, 2023, we recorded $ 0.5 million, in *research and development expense,* on the condensed consolidated statements of operations related to the sponsored research agreement. During the nine months ended September 30, 2024 and 2023, we recorded $ 0.8 million and $ 0.7 million, respectively, in *research and development expense,* on the condensed consolidated statements of operations related to the sponsored research agreement.

LadRx Corporation

In 2017, we entered into an agreement with LadRx pursuant to which we obtained a royalty-bearing, exclusive, worldwide license, with the right to sublicense, LadRx's applicable intellectual property to research, develop and commercialize aldoxorubicin for all indications. On June 3, 2024, ImmunityBio, together with NantCell, entered into a mutual termination of the 2017 license agreement with LadRx that became effective immediately. As of the effective date, any licenses granted to us under the agreement were terminated, and we ceased the development, manufacture, and commercialization of aldoxorubicin.

Acquisition

Dunkirk Facility Leasehold Interest

On February 14, 2022, we completed the acquisition of the Dunkirk Facility (approximately 409,000 rentable square feet) from Athenex, which we believe will provide us with a state-of-the-art biotech production center that will substantially expand and diversify our existing manufacturing capacity in the U.S. and the ability to scale production associated with certain of our product candidates. The company accounted for the transaction as an asset acquisition because the Dunkirk Facility's integrated set of assets and activities did not meet the definition of a business.

Upon the closing of the Dunkirk transaction, the company became the tenant of the Dunkirk Facility under the Fort Schuyler Management Corporation Lease, dated October 1, 2021 (the Commencement Date) and as amended as of the February 14, 2022 closing date (as amended, the Dunkirk Lease), with the FSMC as landlord. The Dunkirk Facility, as well as certain equipment, is owned by the FSMC and is leased to us under the Dunkirk Lease. Our annual lease payment will be $ 2.00 per year for an initial 10-year term, with one option to renew the lease under substantially the same terms and conditions for an additional 10-year term. As part of the transaction, we assumed certain of Athenex's obligations under various third-party agreements (the Facility Agreements), subject to the terms and conditions of the purchase agreement by and between the company and Athenex dated as of January 7, 2022, and committed to spend an aggregate of $ 1.52 billion on operational expenses during the initial term, and an additional $ 1.50 billion on operational expenses if we elect to renew the lease for one additional 10-year term. We also committed to hiring 450 employees at the Dunkirk Facility within the first five years of operations, with 300 such employees to be hired within the first 2.5 years following the Commencement Date. We are eligible for certain sales-tax exemption savings during the development of the Dunkirk Facility, and certain property tax savings over the next 20 years, subject to certain terms and conditions, including performance of certain of the obligations described above. Failure to satisfy the obligations over the lease term may give rise to certain remedies of governmental authorities as we have not satisfied the initial employee count requirement described above. These rights and remedies include, for example, termination of the Dunkirk Lease and other Facility Agreements and potential recoupment of a percentage of the grant funding received by Athenex for construction of the facility and other benefits received, subject to the terms and conditions of the applicable agreements. In November 2024, we received written notice from FSMC alleging non-compliance with the initial employee count requirement described above. We are seeking to resolve this matter expeditiously; however, there can be no assurance that we will succeed in doing so.

Although we believe that governmental funding will assist in funding a portion of the further build-out of the Dunkirk Facility, which we estimate to be approximately $ 8.0 million to $ 10.0 million of governmental funding remaining available as of September 30, 2024, there can be no assurance as to the final acceptance and timing of the requests for governmental funding that we submit, and we will need to plan and fund most of the additional build-out of, and purchase additional equipment for, the Dunkirk Facility in connection with our planned full operations. In addition, any future governmental funding will be subject to the eligibility of submitted expenses, as well as our compliance with the obligations that we are subject to pursuant to the agreements with parties regarding the Dunkirk Facility as described above. Further, on May 14, 2023, Athenex, together with certain of its subsidiaries, filed voluntary petitions for relief under Chapter 11 of the United States Bankruptcy Court for the Southern District of Texas (the Athenex Proceedings). We do not know what, if any, impact the Athenex Proceedings will have on any portion of the potential governmental funding remaining for the Dunkirk Facility.

8. Commitments and Contingencies

Contingent Consideration Related to Business Combinations

VivaBioCell, S.p.A.

In April 2015, NantWorks, a related party, acquired a 100 % interest in VivaBioCell through its wholly-owned subsidiary, VBC Holdings for $ 0.7 million, less working capital adjustments. In June 2015, NantWorks contributed its equity interest in VBC Holdings to the company, in exchange for cash consideration equal to its cost basis in the investment. VivaBioCell develops bioreactors and products based on cell culture and tissue engineering in Italy.

In connection with our acquisition of VBC, we are obligated to pay the former owners contingent consideration upon the achievement of certain milestones related to the GMP-in-a-Box technology. If a government agency unconditionally approves the GMP-in-a-Box technology for commercial sale (the regulatory milestone) in the future, we will be obligated to pay an additional approximately $ 2.2 million to the former owners.

Altor BioScience Corporation

In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $ 304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $ 1.0 billion prior to December 31, 2026, with amounts payable in cash or shares of our common stock or a combination thereof. As the transaction was recorded as an asset acquisition, future CVR payments will be recorded when the corresponding events are probable of achievement or the consideration becomes payable. As of September 30, 2024, Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, and his related party hold approximately $ 139.8 million of net sales CVRs, and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. We may be required to pay the other prior Altor stockholders up to $ 164.2 million for their net sales CVRs should they choose to have their CVRs paid in cash instead of common stock.

Litigation

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. If we are served with any such complaints, we will assess at that time any contingencies for which we may need to reserve. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Sorrento Therapeutics, Inc. Litigation

Sorrento, derivatively on behalf of NANTibody filed an action in the Superior Court of California, Los Angeles County (the Superior Court) against the company's subsidiary NantCell, Dr. Soon-Shiong, and Charles Kim. The action alleged that the defendants improperly caused NANTibody to acquire IgDraSol from NantPharma and sought to have the transaction undone and the purchase amount returned to NANTibody. In 2019, we filed a demurrer to several causes of action alleged in the Superior Court action, and Sorrento filed an amended complaint, eliminating Mr. Kim as a defendant and dropping the causes of action we had challenged in our demurrer. Trial had been set to commence in Sorrento's Superior Court action on August 7, 2023, but on July 24, 2023 the Superior Court vacated the August 7, 2023 trial date at the parties' request in light of the pending settlement discussed below.

Also in 2019, the company and Dr. Soon-Shiong filed cross-claims in the Superior Court action against Sorrento and its Chief Executive Officer Henry Ji, asserting claims for fraud, breach of contract, breach of the covenant of good faith and fair dealing, tortious interference with contract, unjust enrichment, and declaratory relief. Our claims alleged that Dr. Ji and Sorrento breached the terms of an exclusive license agreement between the company and Sorrento related to Sorrento's antibody library and that Sorrento did not perform its obligations under the exclusive license agreement. The Superior Court ruled that the company's claims should be pursued in arbitration and that Dr. Soon-Shiong's claims could be pursued in Superior Court.

In 2019, the company, along with NANTibody, filed an arbitration against Sorrento and Dr. Ji asserting our claims relating to the exclusive license agreement. Sorrento filed counterclaims against the company and NANTibody in the arbitration. The hearings in the NANTibody arbitration commenced in April 2021 and concluded in early August 2021. After post-hearing briefing was concluded, the parties were notified on November 30, 2021 that the arbitrator in the NANTibody arbitration had passed away. A substitute arbitrator was appointed on February 25, 2022, and the parties worked with the substitute arbitrator to conclude the proceedings. Additional hearing sessions were held in May and July 2022, and summations took place on August 2, 2022.

On December 2, 2022, the arbitrator issued a final award finding that Sorrento had breached the two exclusive license agreements with NantCell and NANTibody. The arbitrator awarded NantCell approximately $ 156.8 million and NANTibody approximately $ 16.7 million, plus post-award interest accruing at a daily rate. On December 21, 2022, NantCell and NANTibody filed petitions in the Superior Court to confirm the arbitration award; on January 16, 2023, Sorrento filed a response to the petitions and moved to vacate the award. On February 7, 2023, after a hearing, the Superior Court entered orders confirming the arbitration award and denying Sorrento's motion to vacate. The Superior Court entered judgments against Sorrento in the aggregate amount of approximately $ 176.4 million plus 10 % post-judgment interest, of which approximately $ 159.4 million was payable to NantCell, and the remainder of which was payable to NANTibody. On February 13, 2023, Sorrento informed counsel to the company that it had filed a Chapter 11 proceeding in the U.S. District Court for the Southern District of Texas, *In re: Sorrento Therapeutics, Inc., et al.,* Case No. 23-90085 (DRJ), Docket Entry 810.

On June 6, 2023, Sorrento filed a motion in its Chapter 11 proceeding for entry of an order approving and implementing a mediation settlement reached with the company and other entities. The settlement involved two possible scenarios: Either, if Sorrento were to raise an amount needed to pay its debtor in possession lender and its unsecured creditors by August 31, 2023, Sorrento would pay those obligations, including the judgments held by NantCell and NANTibody, by 2:00 p.m. ET on August 31, 2023 and be free to proceed with pending litigation; or, failing that, the judgments would be released, the litigation claims would be released, including, without limitation, the Superior Court action discussed above, Sorrento would relinquish its interests in NANTibody and certain other entities, Sorrento would forfeit its rights to any payments from NantCell arising out of its antibody exclusive license agreement with NantCell (rights to PD-L1), and certain other provisions not impacting the company would be implemented as described in the motion. On August 14, 2023, the United States Bankruptcy Court for the Southern District of Texas issued an order approving the settlement described above, such that the settlement became binding on the parties. As of 2:00 p.m. ET on August 31, 2023, Sorrento had not paid the judgments held by NantCell and NANTibody. Accordingly, in relevant part to the company and NantCell, a mutual release of claims became effective such that the aforementioned judgments were released, the litigation claims were released including, without limitation, the derivative litigation against NantCell described above, Sorrento relinquished its interests in NANTibody, and Sorrento forfeited its rights to any payments from NantCell arising out of its antibody exclusive license agreement with NantCell, including any royalties associated with the company's engineered NK cell therapy in Phase 2 clinical trials, PD-L1 t-haNK. As a result of the settlement, the parties filed dismissals of the litigation matters discussed above. After the settlement, the company's ownership in NANTibody increased from 60 % to 100 %, and, as a result, the carrying amount of the noncontrolling interest of $ 4.2 million was adjusted and recognized in *additional paid-in capital* attributable to the company, on the condensed consolidated statement of stockholders' deficit.

Shenzhen Beike Biotechnology Co. Ltd. Arbitration

In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration. The arbitration relates to a license, development, and commercialization agreement that Altor entered into with Beike in 2014, which agreement was amended and restated in 2017, pursuant to which Altor granted to Beike an exclusive license to use, research, develop and commercialize products based on ANKTIVA in China for human therapeutic uses. In the arbitration, Beike is asserting a claim for breach of contract under the license agreement. Among other things, Beike alleges that we failed to use commercially reasonable efforts to deliver to Beike materials and data related to ANKTIVA. Beike is seeking specific performance and declaratory relief for the alleged breaches. On September 25, 2020, the parties entered into a standstill agreement under which, among other things, the parties affirmed they would perform certain of their obligations under the license agreement by specified dates and agreed that all deadlines in the arbitration were indefinitely extended. The standstill agreement could be terminated by any party on ten calendar days' notice, and upon termination, the parties had the right to pursue claims arising from the license agreement in any appropriate tribunal. On March 20, 2023, we terminated the standstill agreement, and on April 11, 2023, Beike served an amended Request for Arbitration. We served an Answer and Counterclaims on May 19, 2023. Beike served a Reply to our counterclaims on June 21, 2023. Beike served its Statement of Claim on March 22, 2024, and the company served its Statement of Defense and Counterclaim on June 21, 2024, and Beike served its Statement of Defense to the Counterclaim and Reply on August 2, 2024. The hearing in the arbitration is scheduled to begin on June 9, 2025. Given that discovery is in the early stages, it remains too early to evaluate the likely outcome of the case or to estimate any range of potential loss. We believe the claims asserted against the company lack merit and intend to defend the case, and to pursue our counterclaims, vigorously.

Securities Class Action

On June 30, 2023, a putative securities class action complaint, captioned *Salzman v. ImmunityBio, Inc. et al.* , No. 3:23-cv-01216-BEN-WVG, was filed in the U.S. District Court for the Southern District of California against the company and three of its officers and/or directors, asserting violations of Sections 10(b) and 20(a) of the Exchange Act. Stemming from the company's disclosure on May 11, 2023 that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the complaint alleges that the defendants had previously made materially false and misleading statements and/or omitted material adverse facts regarding its third-party CMOs and the prospects for regulatory approval of the BLA. The complaint did not specify the amount of damages being sought. On September 27, 2023, the court appointed a lead plaintiff, approved their selection of lead counsel, and re-captioned the case *In re. ImmunityBio, Inc. Securities Litigation,* No. 3:23-cv-01216. On November 17, 2023, the lead plaintiff filed an amended complaint, which named the same defendants and asserted the same claims as the previous complaint. On January 8, 2024, the defendants filed a motion to dismiss the amended complaint. On June 20, 2024, the court issued an order granting in part and denying in part the motion to dismiss. On July 16, 2024, the lead plaintiff notified the court that he would proceed with his current pleading, and the defendants answered the complaint on August 29, 2024. The company disputes the claims and intends to defend the case vigorously. The company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in this action. If an unfavorable outcome were to occur, it is possible that the impact could be material to the company's results of operations in the period(s) in which any such outcome becomes probable and estimable.

Shareholder Derivative Action

On October 29, 2024, a shareholder derivative action was filed in the U.S. District Court for the Southern District of California against the members of our Board of Directors and certain officers, captioned *Van Luven v. Soon-Shiong et al.* , Case No. 3:24-cv-02014-L-AHG. Plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant to the action. Stemming from the company's May 11, 2023 disclosure that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the derivative complaint alleges that the individual defendants authorized or permitted materially false and misleading statements and/or omitted material adverse facts regarding ImmunityBio's third-party CMOs and the prospects for regulatory approval of the ANKTIVA BLA. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages on behalf of the company, disgorgement or restitution, declaratory relief, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees.

Commitments

During the nine months ended September 30, 2024, we did not enter into any significant contracts, other than those disclosed in these condensed consolidated financial statements.

In addition, we are also a party to various contracts with CROs and CMOs that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement. There have been no material changes in unconditional purchase commitments from those disclosed in Note 7, *Commitments and Contingencies,* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of our Annual Report filed with the SEC on March 19, 2024.

9. Lease Arrangements

We lease property in multiple facilities across the U.S. and Italy, including facilities located in El Segundo, CA and the Dunkirk Facility in upstate New York. Substantially all of our operating lease right-of-use assets and operating lease liabilities relate to facilities leases. All of our finance leases were related to equipment rental at the Dunkirk Facility. See Note 12, *Related-Party Agreements*, for more information about our related-party leases.

Our leases generally have initial terms ranging from two to ten years and often include one or more options to renew. These renewal terms can extend the lease term from one to ten years and are included in the lease term when it is reasonably certain that we will exercise the option.

Supplemental balance sheet information related to our leases is as follows (in thousands):

	Classification	September 30, 2024 (Unaudited)	December 31, 2023
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 34,946	$ 36,543
Finance lease assets	Other assets	—	58
Total lease assets		$ 34,946	$ 36,601
Liabilities			
Current:			
Operating lease liabilities	Operating lease liabilities	$ 7,033	$ 5,244
Finance lease liabilities	Accrued expenses and other liabilities	—	64
Noncurrent:			
Operating lease liabilities	Operating lease liabilities, less current portion	36,761	39,942
Total lease liabilities		$ 43,794	$ 45,250

Information regarding our lease terms is as follows:

	September 30, 2024 (Unaudited)	December 31, 2023
Weighted-average remaining lease term:		
Operating leases	5.5 years	6.2 years
Finance leases	0 years	0.8 years
Weighted-average discount rate:		
Operating leases	10.9 %	10.9 %
Finance leases	—	11.7 %

The components of lease expense consist of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Operating lease costs	$ 2,558	$ 2,768	$ 7,583	$ 8,611
Short-term lease costs	1,069	997	3,196	3,026
Finance lease costs (including right-of-use asset amortization and interest expense)	18	21	59	66
Variable lease costs	969	977	2,882	2,922
Total lease expense	$ 4,614	$ 4,763	$ 13,720	$ 14,625

Cash paid for amounts included in the measurement of lease liabilities is as follows (in thousands):

	Nine Months Ended September 30,	
	2024	2023
	(Unaudited)	
Cash paid for operating leases (excluding variable lease costs)	$ 7,868	$ 7,713
Financing cash flow from finance leases	$ 64	$ 57
Operating cash flow from finance leases	$ 2	$ 9

Future minimum lease payments as of September 30, 2024, including $ 11.5 million related to options to extend lease terms that are reasonably certain of being exercised, are presented in the following table (in thousands). Common area maintenance costs and taxes are not included in these payments.

Years ending December 31:	Operating Leases
2024 (excluding the nine months ended September 30, 2024)	$ 2,960
2025	11,591
2026	9,728
2027	8,984
2028	9,248
Thereafter	16,057
Total future minimum lease payments	58,568
Less: Interest	14,300
Less: Tenant improvement allowance receivable	474
Present value of lease liabilities	$ 43,794

There have been no material changes related to our existing lease agreements from those disclosed in Note 8, *Lease Arrangements* , of the “Notes to Consolidated Financial Statements” that appears in Part II, Item 8. “Financial Statements and Supplementary Data” of our Annual Report filed with the SEC on March 19, 2024.

10. Revenue Interest Purchase Agreement

Revenue Interest Liability

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain initial Revenue Interests from us for a gross purchase price of $ 200.0 million paid on closing, less $ 7.5 million of issuance costs. Oberland had the option to purchase additional Revenue Interests from us in exchange for a $ 100.0 million Second Payment upon satisfaction of certain conditions in the RIPA, including receipt of approval by the FDA of our BLA for ANKTIVA on or before June 30, 2024.

On April 22, 2024, the FDA approved our product ANKTIVA and as a result, on May 13, 2024 Oberland purchased additional Revenue Interests from us for a gross purchase price of $ 100.0 million, less $ 3.1 million of issuance costs. The issuance costs incurred are being amortized to interest expense over the estimated term of the debt.

As consideration for the aforementioned payments, Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, a certain percentage of our net sales during such quarter, which are tiered payments ranging from 4.5 % to 10.0 % (before funding of the Second Payment, 3.0 % to 7.0 %) of the company's worldwide net sales, excluding those in China.

If the aggregate Revenue Interest Payments made to Oberland as of December 31, 2029 (Test Date) equal or exceed the Cumulative Purchaser Payments ($ 300.0 million) as of that date, the initially tiered revenue interest rate will be decreased to a single rate of 1.50 % (now after the funding of the Second Payment, 2.25 %) of the company's worldwide net sales, excluding those in China. If the aggregate Revenue Interest Payments made to Oberland as of the Test Date are less than the aggregate amount of Cumulative Purchaser Payments as of the Test Date, then following the Test Date the initially tiered revenue interest rate will increase to a rate that, had such increased rate applied during the period from December 29, 2023 through December 31, 2029, it would have resulted in Oberland receiving aggregate Revenue Interest Payments (excluding certain payments detailed in the RIPA) equal to the Cumulative Purchaser Payments as of the Test Date. In addition, if aggregate Revenue Interest Payments made to Oberland as of the Test Date are less than the aggregate amount of Cumulative Purchaser Payments as of the Test Date, then the company must make the True-Up Payment.

Oberland's rights to receive Revenue Interest Payments under the RIPA shall terminate when Oberland has received payments (including any True-Up Payment) equal to 195.0 % of the then Cumulative Purchaser Payments unless the RIPA is terminated prior to such date (subject to certain Call/Put Option scenarios as described below). If Oberland has not received total payments (including any True-Up Payment) equal to 195.0 % of the then Cumulative Purchaser Payments on or before the twelfth anniversary of the RIPA, then the company shall be obligated to pay to Oberland an amount equal to 195.0 % of the then Cumulative Purchaser Payments less the aggregate payments (including any True-Up Payments) made as of such date.

The company's obligations under the RIPA are guaranteed by certain of its subsidiaries meeting materiality thresholds set forth in the RIPA. To secure the company's obligations under the RIPA and the subsidiary guarantors' obligations under the guarantees, each of the company and the subsidiary guarantors has granted a security interest in substantially all its assets, subject to certain exceptions and limitations.

The RIPA contains affirmative and negative covenants and events of default, including covenants and restrictions that, among other things, restrict our ability to incur additional liens, incur additional indebtedness, make loans and investments, enter into transactions with affiliates, engage in mergers and acquisitions, engage in asset sales and exclusive licensing arrangements, and declare dividends to our stockholders, in each case, subject to certain exceptions set forth in the RIPA. As of September 30, 2024, the company was in compliance with all covenants.

The RIPA is considered a sale of future revenues and is accounted for as long-term debt recorded at amortized cost using the effective interest rate method. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales may materially impact the revenue interest liability, interest expense, other income, and the time period for repayment.

During the three and nine months ended September 30, 2024, we recorded $ 10.9 million and $ 28.2 million of interest expense, respectively, related to this arrangement.

The following table summarizes the revenue interest liability activity during the nine months ended September 30, 2024 (in thousands):

	(Unaudited)
Revenue interest liability, at December 31, 2023	$ 155,415
Proceeds from Second Payment, net of issuance costs	96,956
Embedded contingent derivative liability related to Second Payment	(6,150)
Revenue interest payment	(439)
Accrued revenue interest payment	(279)
Interest expense recognized	28,154
Revenue interest liability, at September 30, 2024	$ 273,657

Embedded Derivative Liabilities

Under the RIPA, the company has a Call Option to terminate the RIPA and repurchase the Revenue Interests at any time upon advance written notice, subject to certain limitations set forth in the RIPA. Additionally, Oberland has a Put Option enabling them to terminate the RIPA and to require the company to repurchase the Revenue Interests upon enumerated events, such as a bankruptcy event, failure to make a payment, an uncured material breach, default in certain third-party agreements, a breach or default under any subordination agreements with respect to indebtedness to existing stockholders, or subordinated notes during certain time periods, judgments in excess of certain amounts against the company, a material adverse effect, the loss of regulatory approval of our product candidates or a change of control.

The required purchase price with respect to the Call Option and/or Put Option, as applicable, shall be (a) 120.0 % of the Cumulative Purchaser Payments as of such date, if Oberland exercises the Put Option (other than in connection with a change of control) on or prior to the first anniversary the Closing Date, (b) 135.0 % of the Cumulative Purchaser Payments as of such date, if the Put Option or the Call Option is exercised in connection with a change of control on or prior to the date that is eighteen (18) months after the Closing Date, and (c) in all other cases, (i) 175.0 % of the Cumulative Purchaser Payments as of such date, if the Put Option or the Call Option is exercised no later than the date that is thirty six (36) months after the Closing Date, and (ii) 195.0 % of the Cumulative Purchaser Payments as of such date, if the Put Option or the Call Option is exercised later than the date that is thirty six (36) months after the Closing Date, minus, in each case, the total payments made to Oberland on or prior to such date.

The aforementioned Call and Put Options are considered embedded derivatives requiring bifurcation as a single compound derivative instrument. The company estimated the fair value of the derivative liability using a “with-and-without” method. The with-and-without methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative is the fair value of the derivative liability.

The company recorded $ 34.5 million for the initial fair value of the derivative liability upon the closing of the initial $ 200.0 million Revenue Interests acquired by Oberland. The company recorded an incremental $ 6.2 million for the fair value of the derivative liability upon the closing of the additional $ 100.0 million Revenue Interests acquired by Oberland in May 2024. The initial and incremental fair value allocated to the derivative liability is recorded against the RIPA as a debt discount, which is being amortized in *interest expense,* on the condensed consolidated statement of operations over the expected term of the debt using the effective interest method. The embedded derivative is subsequently remeasured at fair value each reporting period, with the change in fair value being recorded in *change in fair value of derivative liabilities* , on the condensed consolidated statement of operations.

The estimated probability and timing of underlying events triggering the exercisability of the Put Option contained in the RIPA, forecasted cash flows and the discount rate are significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. As of September 30, 2024 and December 31, 2023, the discount rate used for valuation of the derivative liability was 11.7 % and 12.1 %, respectively.

The change in fair value of the derivative liabilities is as follows (in thousands):

	(Unaudited)
Fair value, at December 31, 2023	$ 34,500
Change in fair value	2,630
Fair value, at March 31, 2024	37,130
Embedded contingent derivative liability related to Second Payment	6,150
Change in fair value	(23,440)
Fair value, at June 30, 2024	19,840
Change in fair value	(2,220)
Fair value, at September 30, 2024	$ 17,620

Stock Purchase and Option Agreement

In connection with the RIPA, we entered into an SPOA with Oberland pursuant to which we sold an aggregate of approximately $ 10.0 million of our common stock at $ 4.1103 per share in a private placement. Oberland also had an option to purchase up to an additional $ 10.0 million of our common stock, at a price per share to be determined by reference to the 30-day trailing volume weighted-average price of our common stock calculated from the date of exercise.

This stock purchase option was classified as a liability estimated at fair value at issuance. The initial $ 200.0 million received pursuant to the RIPA and $ 10.0 million received pursuant to the SPOA were allocated among the resulting financial instruments on a relative fair value basis, with $ 197.1 million allocated to the debt under the RIPA, $ 12.0 million allocated to the common stock issued under the SPOA, and $ 0.8 million allocated to the stock purchase option as of December 31, 2023.

In April 2024, Oberland exercised part of their option and purchased 858,990 shares of our common stock at an exercise price of $ 5.8208 per share generating net proceeds of approximately $ 4.9 million. Following such exercise, approximately $ 5.0 million remains available for future exercise under the SPOA as of September 30, 2024.

This stock purchase option is classified in *accrued expenses and other liabilities* , on the condensed consolidated balance sheet at its fair value and is subsequently remeasured at fair value each reporting period, with the change in fair value being recorded in *change in fair value of derivative liabilities* , on the condensed consolidated statement of operations.

The change in fair value of the stock option purchase liability is as follows (in thousands):

	(Unaudited)
Fair value, at December 31, 2023	$ 819
Change in fair value	127
Fair value, at March 31, 2024	946
Exercise of stock option	(2,705)
Change in fair value	2,079
Fair value, at June 30, 2024	320
Change in fair value	(30)
Fair value, at September 30, 2024	$ 290

11. Related-Party Debt

Our related-party debt is summarized below (in thousands):

	Balances as of September 30, 2024 (Unaudited)				
	Maturity Year	Interest Rate	Principal Amount	Less: Unamortized Discounts	Total
Related-Party Nonconvertible Note:					
$ 505 million December 2023 Promissory Note Tranche 1(1)	2025	Term SOFR + 8.0 %	$ 125,000	$ 13,857	$ 111,143
Related-Party Convertible Notes:					
$ 505 million December 2023 Promissory Note Tranche 2(1)	2025	Term SOFR + 7.5 %	$ 380,000	$ 22,025	$ 357,975
$ 30 million March 2023 Promissory Note	2025	Term SOFR + 8.0 %	30,000	—	30,000
$ 200 million September 2023 Promissory Note	2026	Term SOFR + 8.0 %	200,000	—	200,000
Total related-party convertible notes			$ 610,000	$ 22,025	$ 587,975

	Balances as of December 31, 2023				
	Maturity Year	Interest Rate	Principal Amount	Less: Unamortized Discounts	Total
Related-Party Nonconvertible Note:					
$ 505 million December 2023 Promissory Note Tranche 1(1)	2025	Term SOFR + 8.0 %	$ 125,000	$ 20,414	$ 104,586
Related-Party Convertible Notes:					
$ 505 million December 2023 Promissory Note Tranche 2(1)	2025	Term SOFR + 7.5 %	$ 380,000	$ 33,049	$ 346,951
$ 30 million March 2023 Promissory Note	2025	Term SOFR + 8.0 %	30,000	—	30,000
$ 200 million September 2023 Promissory Note	2026	Term SOFR + 8.0 %	200,000	—	200,000
Total related-party convertible notes			$ 610,000	$ 33,049	$ 576,951

(1) The discounts on our $ 505 million December 2023 Promissory Note were based on imputed interest rates of 23.65 % for Tranche 1 and 18.04 % for Tranche 2, respectively, calculated as of December 2023.

$ 505 million December 2023 Promissory Note

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into an amended and restated promissory note. Pursuant to the terms of the amended and restated promissory note, the amended promissory note has an aggregate principal amount of $ 505.0 million, comprised of Tranche 1 with a principal amount of $ 125.0 million, and Tranche 2 with a principal amount of $ 380.0 million. The maturity date of the amended promissory note is December 31, 2025.

$ 125.0 million principal amount of Tranche 1 of the promissory note bears an interest rate of Term SOFR plus 8.0 % per annum, payable on a quarterly basis. The company may prepay the outstanding principal amount, at any time, in whole or in part, without penalty.

$ 380.0 million principal amount of Tranche 2 of the promissory note bears an interest rate of Term SOFR plus 7.5 % per annum, payable on a quarterly basis. The Tranche 2 promissory note provides that the noteholder has the sole option to convert all (but not less than all) of the outstanding principal amount of $ 380.0 million and accrued but unpaid interest into shares of the company's common stock at a conversion price of $ 8.2690 per share, subject to appropriate adjustment from time to time for any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification or other similar event. In addition, the noteholder can request up to $ 50.0 million of the Tranche 2 principal amount and accrued interest to be repaid upon consummation of a specified transaction.

The amended and restated December 2023 promissory note includes an embedded derivative related to a contingently exercisable prepayment feature, which allows the noteholder to request up to a $ 50.0 million prepayment and accrued interest upon occurrence of a specified transaction (defined in the promissory note). The fair value of the derivative liability is determined at each period end using the with-and-without method, which assesses the likelihood and timing of a specified transaction that if triggered could result in a repayment. This embedded derivative is recorded as a derivative liability on the condensed consolidated balance sheet and is measured at fair value. Changes in the fair value of the derivative liability are reported as *change in fair value of derivative liabilities*, on the condensed consolidated statement of operations. The fair value of the embedded derivative is remeasured to fair value at each reporting date until the derivative is settled.

The change in fair value of the contingently exercisable prepayment feature embedded derivative is as follows (in thousands):

	(Unaudited)
Fair value, at December 31, 2023	$ 833
Change in fair value	(33)
Fair value, at March 31, 2024	800
Change in fair value	167
Fair value, at June 30, 2024	967
Change in fair value	636
Fair value, at September 30, 2024	$ 1,603

$ 30 million March 2023 Promissory Note

On March 31, 2023, the company executed a $ 30.0 million promissory note with Nant Capital. This note bears interest at Term SOFR plus 8.0 % per annum, payable on a quarterly basis. The outstanding principal amount and any accrued and unpaid interest was originally due on December 31, 2023. The company may prepay the outstanding promissory note, at any time, in whole or in part, without penalty. Upon receipt of a written notice of prepayment from the company, the noteholder may choose to convert the outstanding principal amount to be prepaid and the accrued and unpaid interest thereon into shares of the company's common stock at a price of $ 2.28 per share. Additionally, the noteholder may at its option convert the entire outstanding principal amount of the promissory note and accrued interest into shares of the company's common stock at a conversion price of $ 2.28 per share, at the option of the noteholder.

On September 11, 2023, the company and Nant Capital entered into a letter agreement pursuant to which the maturity date of the $ 30.0 million promissory note described above was extended from December 31, 2023 to December 31, 2024.

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into a letter agreement pursuant to which the maturity date of this promissory note was extended to December 31, 2025.

Prior to December 29, 2023, the $ 30.0 million March 2023 promissory note was accounted for under the ASC 825-10-15-4 FVO election. Under the FVO election, the note was initially measured at its issue-date estimated fair value and subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. On December 29, 2023, all outstanding promissory notes were modified and accounted for as a debt extinguishment. After the debt extinguishment, the note is accounted for under the amortized cost basis. As of September 30, 2023, the estimated fair value of the convertible note was computed using a binomial lattice model with the following unobservable assumptions:

	September 30, 2023 (Unaudited)
Expected market yield	25.2 %
Volatility	100.8 %
Risk-free rate	5.4 %

$ 200 million September 2023 Promissory Note

On September 11, 2023, the company executed a $ 200.0 million convertible promissory note with Nant Capital. The note bears interest at Term SOFR plus 8.0 % per annum, payable on a monthly basis. The outstanding principal amount and any accrued and unpaid interest are due on September 11, 2026. We may prepay the outstanding principal amount, together with any accrued interest, at any time, in whole or in part, without premium or penalty upon five (5) days written notice to the noteholder. The noteholder has the sole option to convert all (but not less than all) of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $ 1.9350 per share.

In connection with the RIPA transaction, all outstanding related-party promissory notes became subordinated to the RIPA payment obligations.

The following table summarizes the estimated future contractual obligations for our related-party debt as of September 30, 2024 (in thousands):

	Principal Payments		Interest Payments (1)		
	Convertible Notes	Nonconvertible Note	Convertible Notes	Nonconvertible Note	Total
	(Unaudited)				
2024 (excluding the nine months ended September 30, 2024)	$ —	$ —	$ 19,010	$ 3,968	$ 22,978
2025	410,000	125,000	75,421	15,742	626,163
2026	200,000	—	17,876	—	217,876
Total	$ 610,000	$ 125,000	$ 112,307	$ 19,710	$ 867,017

(1) Interest payments on our promissory notes are calculated based on Term SOFR plus the contractual spread per the loan agreements. The weighted-average interest rate on our promissory notes as of September 30, 2024 was 12.40 %.

12. Related-Party Agreements

We conduct business with several affiliates under written agreements and informal arrangements. Below is a summary of outstanding balances and a description of significant relationships (in thousands):

	September 30, 2024 (Unaudited)	December 31, 2023
Due from related party–NantWorks	$ 536	$ 541
Due from related party–Brink	125	62
Due from related party–NantBio	—	1,294
Due from related parties–Various	68	122
Total due from related parties	$ 729	$ 2,019
Due to related party–Duley Road	$ 133	$ 136
Due to related party–the Clinic	235	57
Due to related party–NantBio	—	943
Due to related party–Various	18	—
Total due to related parties	$ 386	$ 1,136

Our Executive Chairman and Global Chief Scientific and Medical Officer founded and has a controlling interest in NantWorks, which is a collection of companies in the healthcare and technology space. As described below, we have entered into arrangements with NantWorks, and certain affiliates of NantWorks, to facilitate the development of new immunotherapies for our product pipeline. Affiliates of NantWorks are also affiliates of the company due to the common control by and/or common ownership interest of our Founder, Executive Chairman, Global Chief Scientific and Medical Officer, and principal stockholder.

NantWorks, LLC

Shared Services Agreement

Under the amended and restated shared services agreement with NantWorks dated as of June 2016, but effective as of August 2015, NantWorks, a related party, provides corporate, general and administrative, certain research and development, and other support services to us, and we provide certain of such services to them. The receiving party is charged for the services at cost plus reasonable allocations of employee benefits, facilities, and other direct or fairly allocated indirect costs that relate to the employees providing the services. During the three months ended September 30, 2024 and 2023, we recorded $ 0.7 million and $ 0.5 million, respectively, in *selling, general and administrative expense*, and $ 0.9 million and $ 0.6 million of expense reimbursements, respectively, under this arrangement in *research and development expense*, on the condensed consolidated statements of operations. During the nine months ended September 30, 2024 and 2023, we recorded $ 1.7 million and $ 2.4 million, respectively, in *selling, general and administrative expense*, and $ 2.2 million and $ 1.6 million of expense reimbursements, respectively, under this arrangement in *research and development expense*, on the condensed consolidated statements of operations. These amounts exclude certain general and administrative expenses provided by third-party vendors directly for our benefit, which were reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

As of September 30, 2024 and December 31, 2023, we had a receivable of $ 0.5 million and $ 0.5 million, respectively, for all agreements with NantWorks, which are included in *due from/due to related parties,* on the condensed consolidated balance sheets. We also recorded $ 1.3 million and $ 1.0 million of prepaid expenses for various services that we expect will be passed through to the company from NantWorks as of September 30, 2024 and December 31, 2023, respectively, which are included in *prepaid expenses and other current assets*, on the condensed consolidated balance sheets.

Facility License Agreement

In 2015, we entered into a facility license agreement with NantWorks for approximately 9,500 rentable square feet of office space in Culver City, California, which was converted to a research and development laboratory and a cGMP manufacturing facility. In 2020, we amended this agreement to extend the term of this license agreement through December 31, 2021. Commencing on January 1, 2022, the license fee increased by 3 % to approximately $ 56,120 per month.

On May 6, 2022, we amended our facility license agreement with NantWorks to expand the licensed premises by 36,830 rentable square feet to an aggregate total of 46,330 rentable square feet. Effective May 1, 2022, the license fee is approximately $ 273,700 per month, which is subject to a 3 % increase commencing on January 1 of each year. The space continues to be rented on a month-to-month basis, which can be terminated by either party with at least 30 days' prior written notice to the other party. We recorded license fee expense for this facility totaling $ 0.9 million and $ 0.8 million during the three months ended September 30, 2024 and 2023, respectively, and $ 2.6 million and $ 2.5 million during the nine months ended September 30, 2024 and 2023, respectively, in *research and development expense* , on the condensed consolidated statements of operations.

Immuno-Oncology Clinic, Inc.

We have entered into multiple agreements with t he Clinic to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by an officer of the company and NantWorks manages the administrative operations of the Clinic.

In 2021, we completed a review of alternative structures that could support our more complex clinical trial requirements and made a decision to explore a potential transition of clinical trials at the Clinic to a new structure (including contracting with a new, non-affiliated professional corporation) to be determined and agreed upon by all parties. We continue discussions with potential partners around alternative structures.

Related to clinical trial and transition services provided by the Clinic, we recorded $ 0.7 million and $ 0.5 million during the three months ended September 30, 2024 and 2023, respectively, and $ 2.1 million and $ 1.9 million, respectively, during the nine months ended September 30, 2024 and 2023 in *research and development expense* , on the condensed consolidated statements of operations. As of September 30, 2024 and December 31, 2023, we owed the Clinic $ 0.2 million and $ 0.1 million, respectively, which are included in *due to related parties,* on the condensed consolidated balance sheets .

NantBio, Inc.

In August 2018, we entered into a supply agreement with NCSC, a 100% owned subsidiary of NantBio. Under this agreement, we agreed to supply VivaBioCell's proprietary GMP-in-a-Box bioreactors and related consumables, made according to specifications mutually agreed to with both companies. The agreement has an initial term of five years and renews automatically for successive one-year terms unless terminated by either party in the event of material default upon prior written notice of such default and the failure of the defaulting party to remedy the default within 30 days of the delivery of such notice, or upon 90 days' prior written notice by NCSC.

During the three and nine months ended September 30, 2024 and 2023, we recognized no revenue. As of September 30, 2024 and December 31, 2023, we recorded $ 0.1 million of deferred revenue for bioreactors that were delivered but not installed in *accrued expenses and other liabilities* , on the condensed consolidated balance sheets. As of December 31, 2023, we recorded a payable of $ 0.9 million in *due to related parties* , on the condensed consolidated balance sheets related to this agreement. The payable was settled as of June 30, 2024.

In 2018, we entered into a shared service agreement pursuant to which we are charged for services at cost, without mark-up or profit by NantBio, but including reasonable allocations of employee benefits that relate to the employees providing the services. In April 2019, we agreed with NantBio to transfer certain NantBio employees and associated research and development projects to the company. As of December 31, 2023, we recorded a receivable of $ 1.3 million in *due from related parties* on the condensed consolidated balance sheets for amounts we paid on behalf of NantBio during the year ended December 31, 2019. The receivable was settled as of June 30, 2024.

605 Doug St, LLC

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, an entity owned by our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, for approximately 24,250 rentable square feet in El Segundo, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. The lease term was from July 2016 through July 2023. In June 2023, we exercised the option to extend the lease for one additional three-year term through July 2026. The base rent is approximately $ 72,385 per month, with annual increases of 3 % that began in July 2017. We recorded lease expense for this facility of $ 0.2 million during the three months ended September 30, 2024 and 2023, and $ 0.7 million during the nine months ended September 30, 2024 and 2023 in *research and development expense*, on the condensed consolidated statements of operations.

Duley Road, LLC

In February 2017, we entered into a lease agreement with Duley Road, a related party that is indirectly controlled by our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, for approximately 11,980 rentable square feet of office and cGMP manufacturing facility space in El Segundo, California. The lease term was originally from February 2017 through October 2024. We had and continue to have the option to extend the initial term for two consecutive five-year periods through October 2034. The base rent is approximately $ 40,700 per month, with annual increases of 3 %. Effective October 3, 2023, we exercised the first option to extend the lease for one additional five-year term through October 31, 2029.

Effective in January 2019, we entered into two lease agreements with Duley Road for a second building located in El Segundo, California. The first lease is for the first floor of the building with approximately 5,650 rentable square feet. The lease has a seven-year term commencing in September 2019. The second lease is for the second floor of the building with approximately 6,488 rentable square feet. The lease has a seven-year term commencing in July 2019. Both floors of the building are used for research and development and office space. We have options to extend the initial terms of both leases for two consecutive five-year periods through 2036. The base rent for the two leases is approximately $ 35,800 per month, with annual increases of 3 %.

During the three months ended September 30, 2024 and 2023, we recorded rent expense for these leases totaling $ 0.2 million in *research and development expense*, on the condensed consolidated statements of operations. During the nine months ended September 30, 2024 and 2023, we recorded rent expense for these leases totaling $ 0.7 million and $ 0.6 million, respectively, in *research and development expense*, on the condensed consolidated statements of operations. As of September 30, 2024 and December 31, 2023, we recorded $ 0.1 million of lease-related payables to Duley Road in *due to related parties*, on the condensed consolidated balance sheets.

605 Nash, LLC

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, a related party, whereby we leased approximately 6,883 rentable square feet (the Initial Premises) in a two-story mixed-use building containing approximately 64,643 rentable square feet at 605-607 Nash Street in El Segundo, California. This facility is used primarily for pharmaceutical development and manufacturing purposes. The lease term commenced in January 2021 and was originally set to expire in December 2027 and included an option to extend the lease for one three-year term through December 2030. The base rent is approximately $ 20,300 per month with an annual increase of 3 % on January 1 of each year during the initial term and, if applicable, during the option term. In addition, under the agreement, we are required to pay our share of estimated property taxes and operating expenses.

In May 2021, but effective on April 1, 2021, we entered into an amendment to our Initial Premises lease with 605 Nash. The amendment expanded the leased square feet by approximately 57,760 rentable square feet (the Expansion Premises). The lease term of the Expansion Premises commenced in April 2021 and expires in March 2028, whereby the company has one option to extend the initial term for three years . Per the terms of the amendment, the term of the Initial Premises lease was extended for an additional three months and now expires on March 31, 2028. Base rent for the Expansion Premises is approximately $ 170,400 per month with annual increases of 3 % on April 1 of each year. We are responsible for the build out of the facility space and associated costs.

We recorded rent expense for the Initial and Expansion Premises leases totaling $ 0.5 million during the three months ended September 30, 2024 and 2023, and $ 1.6 million during the nine months ended September 30, 2024 and 2023 in *research and development expense,* on the condensed consolidated statements of operations. The terms of the initial and amended leases provided for tenant improvement allowances totaling $ 2.9 million for costs and expenses related to improvements made by us to the Initial and Expansion Premises, which was received from the landlord in 2023.

420 Nash, LLC

On September 27, 2021, we entered into a lease agreement with 420 Nash, LLC, a related party, whereby we leased an approximately 19,125 rentable square foot property located at 420 Nash Street, El Segundo, California, to be used primarily for the warehousing and storage of drug manufacturing supplies, products and equipment and ancillary office space.

Under the terms of the lease agreement, the lease term began on October 1, 2021 and expires on September 30, 2026. The base rent is approximately $ 38,250 per month with an annual increase of 3 % on October 1 of each year beginning in 2022 during the initial term. The company is responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance and operating expenses during the term of the lease.

The company has options to extend the lease term for two additional consecutive periods of five years each. At the beginning of each option term, the initial monthly base rent will be adjusted to market rent (as defined in the lease agreement) with an annual increase of 3 % during the option term. We have included the first option to extend the lease term for five years as part of the initial term of the lease as it is reasonably certain that we will exercise the option, which implies lease expiration in September 2031. We recorded rent expense of $ 0.1 million for this lease during the three months ended September 30, 2024 and 2023, and $ 0.4 million during the nine months ended September 30, 2024 and 2023 in *research and development expense*, on the condensed consolidated statements of operations.

23 Alaska, LLC

On May 6, 2022, we entered into a lease agreement with 23 Alaska, LLC, a related party, for a 47,265 rentable square foot facility located at 2335 Alaska Ave., El Segundo, California, to be used primarily for pharmaceutical development and manufacturing, research and development, and office space.

Under the terms of the agreement, the lease term began on May 1, 2022 and was to expire on April 30, 2027. The base rent was approximately $ 139,400 per month with an annual increase of 3 % on May 1 of each year beginning in 2023 during the initial term. We were also required to pay $ 7,600 per month for parking during the initial term. The company was responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance, and operating expenses during the term of the lease.

Effective August 31, 2023, we executed a lease termination agreement with the lessor under which we received a full refund of the security deposit totaling $ 0.1 million that we paid upon execution of the lease. During the three and nine months ended September 30, 2023, we recorded $ 0.3 million and $ 1.2 million of rent expense for this lease, respectively, in r *esearch and development expense* , on the condensed consolidated statements of operations.

13. Warrant Liabilities

December 2022 Warrants

In connection with the December 12, 2022 RDO, the company issued 9,090,909 warrants with an exercise price of $ 6.60 per share. These warrants were classified as a liability at their fair value upon issuance. The warrants became immediately exercisable on December 12, 2022 and expire on December 12, 2024.

February 2023 Warrants

In connection with the February 15, 2023 RDO, the company issued 14,072,615 warrants with an amended exercise price of $ 3.2946 per share. These warrants were classified as a liability at their fair value upon issuance. The warrants became immediately exercisable on February 17, 2023 and expire on July 24, 2026.

During the three months ended September 30, 2024, institutional holders exercised a total of 4,740,249 warrants pursuant to the February 2023 Warrant agreement at an exercise price of $ 3.2946 per share resulting in the issuance of 4,740,249 shares of the company's common stock for proceeds totaling $ 15.6 million.

July 2023 Warrants

In connection with the July 20, 2023 RDO, the company issued 14,569,296 warrants with an exercise price of $ 3.2946 per share. These warrants were classified as a liability at their fair value upon issuance. These warrants became immediately exercisable on July 25, 2023 and expire on July 24, 2026.

Warrant Liabilities

The following table summarizes the change in carrying amount of warrant liabilities measured at fair value during the nine months ended September 30, 2024 (in thousands):

	Total	December 2022 Warrants	February 2023 Warrants	July 2023 Warrants
	(Unaudited)			
Fair value, at December 31, 2023	$ 118,770	$ 17,091	$ 49,958	$ 51,721
Warrant exercises	(10,585)	—	—	(10,585)
Change in fair value	1,802	(636)	4,081	(1,643)
Fair value, at March 31, 2024	109,987	16,455	54,039	39,493
Warrant exercises	(63,892)	—	(30,320)	(33,572)
Change in fair value	19,300	818	8,917	9,565
Fair value, at June 30, 2024	65,395	17,273	32,636	15,486
Warrant exercises	(15,763)	—	(15,763)	—
Change in fair value	(31,324)	(16,818)	(9,021)	(5,485)
Fair value, at September 30, 2024	$ 18,308	$ 455	$ 7,852	$ 10,001

Warrant Exercises

The following table summarizes warrant exercise activity during the nine months ended September 30, 2024:

	Total	December 2022 Warrants	February 2023 Warrants	July 2023 Warrants
	(Unaudited)			
Warrants outstanding, at December 31, 2023	37,732,820	9,090,909	14,072,615	14,569,296
Warrant exercises	(4,284,648)	—	—	(4,284,648)
Warrants outstanding, at March 31, 2024	33,448,172	9,090,909	14,072,615	10,284,648
Warrant exercises	(13,217,843)	—	(6,517,843)	(6,700,000)
Warrants outstanding, at June 30, 2024	20,230,329	9,090,909	7,554,772	3,584,648
Warrant exercises	(4,740,249)	—	(4,740,249)	—
Warrants outstanding, at September 30, 2024	15,490,080	9,090,909	2,814,523	3,584,648

Warrant Valuation Assumptions

The estimated fair value of the warrants was computed using the Black-Scholes option pricing model with the following unobservable assumptions at the following dates:

	December 2022 Warrants		February and July 2023 Warrants	
	September 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
	(Unaudited)		(Unaudited)	
Exercise price per share	$ 6.60	$ 6.60	$ 3.2946	$ 3.2946
Expected term	0.2 year	1.0 year	1.8 years	2.6 years
Expected average volatility	84.3 %	119.0 %	161.8 %	107.3 %
Expected dividend yield	—	—	—	—
Risk-free interest rate	4.8 %	4.7 %	3.7 %	4.1 %

The expected term is the time remaining until the expiration of the warrants. The expected average volatility was estimated based on the historical and implied volatility of our common stock. The expected dividend yield was based on our expectation of not paying dividends for the foreseeable future. The risk-free interest rate was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

14. Stockholders' Deficit

Stock Repurchases

During the nine months ended September 30, 2024 and 2023, no shares of our common stock were repurchased under the company's 2015 Share Repurchase Program. As of September 30, 2024, $ 18.3 million remained authorized to use for share repurchases under the program.

Shelf Registration Statements

During February 2023, we filed a $ 750.0 million shelf registration statement with the SEC on Form S-3 for the offering and sale of equity and equity-linked securities, including common stock, preferred stock, debt securities, depositary shares, warrants to purchase common stock, preferred stock or debt securities, subscription rights, purchase contracts, and units. As of September 30, 2024, we had $ 565.6 million available for use under the shelf.

During April 2024, we filed a shelf registration statement with the SEC on Form S-3 pursuant to which we may, from time to time, sell up to an indeterminate amount of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units. On May 2, 2024, the registration statement was declared effective by the SEC.

Amounts available for use as of September 30, 2024 under these shelf registration statements are in addition to the amount available under the ATM described below.

Open Market Sale Agreement

In April 2021, we entered into the ATM under which we may offer and sell, from time to time at our sole discretion, shares of our common stock through our sales agent. We pay our sales agent a commission of up to 3.0 % of the gross sales proceeds of any shares of our common stock sold through them under the ATM, and also have provided them with customary indemnification and contribution rights.

In April 2024, the company filed a shelf registration statement and associated prospectus that increased the amount available under the ATM by $ 92.0 million. We received net proceeds totaling $ 2.5 million during the three months ended September 30, 2023 and $ 3.6 million and $ 16.1 million during the nine months ended September 30, 2024 and 2023, respectively, from the issuance of shares under the ATM. As of September 30, 2024, we had $ 296.5 million available for future stock issuances under the ATM.

We are not obligated to sell any shares and may at any time suspend solicitation and offers under the ATM. The ATM may be terminated by us at any time given written notice to the sales agent for any reason or by the sales agent at any time by giving written notice to us for any reason or immediately under certain circumstances and shall automatically terminate upon the issuance and sale of all of the shares.

Stock Purchase and Option Agreement

On December 29, 2023 and in connection with the RIPA, we entered into an SPOA with Oberland. Under this agreement, Oberland had an option to purchase up to $ 10.0 million of our common stock, at a price per share to be determined by reference to the 30-day trailing volume weighted-average price of our common stock, calculated from the date of exercise. The option is exercisable by Oberland at any time until the earliest of (i) December 29, 2028, (ii) a change of control of the company, or (iii) a sale of substantially all of the company's assets. Among other limitations, the option may only be exercised to the extent that the common stock issuable pursuant to such exercise would not exceed 19.9 % of the common stock outstanding immediately after giving effect to such exercise.

Pursuant to the SPOA, in April 2024 Oberland exercised its option to purchase 858,990 shares of our common stock at an exercise price of $ 5.8208 per share generating net proceeds of approximately $ 4.9 million. Following such exercise, approximately $ 5.0 million remains available for future exercise under the SPOA.

15. Stock-Based Compensation

2015 Equity Incentive Plan

At the company's 2024 Annual Meeting of Stockholders held on June 11, 2024, our stockholders approved an amendment to increase the number of shares of common stock authorized for issuance under the 2015 Plan by 19.9 million shares. As of September 30, 2024, approximately 25.6 million shares were available for future grants under the 2015 Plan.

Stock-Based Compensation

The following table presents stock-based compensation included on the condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Stock-based compensation expense:				
Stock options	$ 3,993	$ 3,408	$ 11,599	$ 10,496
RSUs	3,496	11,041	13,795	25,893
	$ 7,489	$ 14,449	$ 25,394	$ 36,389
Stock-based compensation expense in operating expenses:				
Research and development	$ 1,818	$ 5,218	$ 8,960	$ 12,725
Selling, general and administrative	5,671	9,231	16,434	23,664
	$ 7,489	$ 14,449	$ 25,394	$ 36,389

Stock Options

The following table summarizes stock option activity and related information during the nine months ended September 30, 2024:

	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2023	9,820,435	$ 9.46	$ 6,046	6.6
Granted	6,336,675	$ 5.29		
Exercised	(308,959)	$ 2.31		
Forfeited/expired	(396,848)	$ 5.46		
Outstanding at September 30, 2024	15,451,303	$ 7.99	$ 1,940	7.3
Vested and exercisable at September 30, 2024	8,067,425	$ 10.38	$ 1,940	5.7

As of September 30, 2024, the unrecognized compensation cost related to outstanding stock options was $ 24.3 million, which is expected to be recognized over a remaining weighted-average period of 1.9 years.

During the nine months ended September 30, 2024, the total intrinsic value of stock options exercised was $ 0.9 million. During the nine months ended September 30, 2024 and 2023, cash proceeds received from stock option exercises were $ 0.7 million and $ 0.3 million, respectively.

As of December 31, 2023, a total of 5,867,252 vested and exercisable shares were outstanding.

The fair value of stock options issued was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine Months Ended September 30, 2024 (Unaudited)
Expected term	5.96 years
Risk-free interest rate	4.3 %
Expected volatility	116.8 %
Expected dividend yield	—
Weighted-average grant date fair value	$ 4.58

The expected term was estimated using the average of the contractual term and the weighted-average vesting term of the options. The risk-free interest rate was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The expected volatility was estimated based on the historical volatility of our common stock. The expected dividend yield was based on our expectation of not paying dividends for the foreseeable future.

Restricted Stock Units

The following table summarizes RSU activity during the nine months ended September 30, 2024:

	Number of Units		Weighted-Average Grant Date Fair Value
Nonvested balance at December 31, 2023	7,503,979	$	12.01
Granted	3,003,536	$	4.95
Vested	(3,406,609)	$	3.09
Forfeited/canceled	(541,472)	$	13.18
Nonvested balance at September 30, 2024	6,559,434	$	13.32

As of September 30, 2024, there was $ 32.0 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 1.9 years. During the nine months ended September 30, 2024, the total intrinsic value of RSUs vested was $ 12.4 million.

RSUs awarded to employees and consultants of affiliated companies are accounted for as stock-based compensation in accordance with FASB ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, as the compensation was in exchange for continued support or services expected to be provided to the company over the vesting periods under the NantWorks shared services agreement discussed in Note 12, *Related-Party Agreements*. We have evaluated the associated benefit of these awards to the affiliated companies under common control and determined that the benefit is limited to the retention of their employees. We estimated such benefit at the grant date fair value of $ 4.0 million. During the nine months ended September 30, 2024 and 2023, we recorded $ 0.1 million and $ 0.3 million of deemed dividends, respectively, in *additional paid-in capital,* on the condensed consolidated balance sheets, with a corresponding credit to stock-based compensation expense.

Related-Party Warrants

As of September 30, 2024, a total of 1,638,000 warrants with an exercise price of $ 3.24 per warrant were outstanding. The fair value of $ 18.0 million assigned to the warrants will be recognized in equity upon achievement of a performance-based vesting condition pertaining to building manufacturing capacity to support supply requirements for one of our product candidates.

16. Income Taxes

We are subject to U.S. federal income tax, as well as income tax in Italy, South Korea, California and other states. From inception through September 30, 2024, we have not been required to pay U.S. federal and state income taxes because of current and accumulated NOLs. The company computes its quarterly income tax provision using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. No tax benefit was provided for losses incurred in the U.S., Italy, and South Korea because those losses are offset by a full valuation allowance.

Our federal returns for tax years 2021 through 2023 remain open to examination, and our state returns remain subject to examination for tax years 2020 through 2023. The Italian and South Korean returns for tax years 2019 through 2023 remain open to examination. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the IRS or other respective tax authorities. No income tax returns are currently under examination by taxing authorities.

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

Forward-Looking Statements

The following discussion and analysis of our financial condition and results of operations should be read together with the description of our business and the condensed consolidated financial statements and related notes thereto Item 1. "Financial Statements" in this Quarterly Report. This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that are based on our management's beliefs and assumptions and on information currently available to our management. Actual results could differ materially from those discussed in or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Quarterly Report, particularly in Part II, Item 1A. "Risk Factors." Except as required by law, we do not undertake any responsibility to update any of these factors or to announce publicly any revisions to any of the forward-looking statements contained in this or any document, whether as a result of new information, future events, or otherwise. Forward-looking statements include, but are not limited to:

- our ability to successfully commercialize our approved product;
- our ability to obtain incremental approvals for ANKTIVA for new indications from the FDA or clearances or approvals from international regulatory agencies for the treatment of patients with NMIBC or other indications;
- potential futures uses and applications of ANKTIVA and use in cancer vaccines and across multiple tumor types;
- our ability to develop next-generation therapies and vaccines that complement, harness, and amplify the immune system to defeat cancers and infectious diseases;
- our ability to obtain additional financing to fund our operations and complete the commercialization of our approved product and the development and commercialization of our other product candidates;
- our ability to meet our payment obligations under the RIPA and to service the interest on our related-party promissory notes and repay such notes, to the extent required;
- our ability to comply with the terms, conditions, covenants, restrictions, and obligations set forth in the RIPA and related transaction documents;
- our expectations regarding the potential benefits of our strategy and technology;
- our ability to forecast operating results and make period-to-period comparisons predictive of future performance due to fluctuations in warrant values;
- our expectations regarding the operation and effectiveness of our product candidates and related benefits;
- our ability to utilize multiple modes to induce cell death;
- our beliefs regarding the benefits and perceived limitations of competing approaches, and the future of competing technologies and our industry;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design and the enrollment of patients;
- the timing of the development and commercialization of our other product candidates;
- our expectations regarding our ability to utilize the Phase I/II aNK and haNK ® clinical trials data to support the development of our product candidates, including our haNK, taNK, t-haNK™, MSC, and M-ceNK™ product candidates;

- our expectations regarding the development, application, commercialization, marketing, prospects and use generally of our product candidates, including hAd5 and saRNA constructs, and PD-L1 t-haNK and M-ceNK;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses in the U.S. and jurisdictions outside of the U.S., including any planned IND, BLA, NDA or MAA or similar filings or pursuit of accelerated regulatory approval pathways or orphan drug status and *Breakthrough Therapy* designations;
- our ability to implement an integrated discovery ecosystem and the operation of that planned ecosystem, including being able to regularly add neoepitopes and subsequently formulate new product candidates;
- the ability and willingness of strategic collaborators to share our vision and effectively work with us to achieve our goals;
- the ability and willingness of various third parties to engage in R&D activities involving our product candidates, and our ability to leverage those activities;
- our ability to attract additional third-party collaborators;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- our expectations regarding the timing of enrollment and submission of our clinical trials, and protocols related to such trials;
- our ability to produce an antibody-cytokine fusion protein, a DNA, RNA, or recombinant protein vaccine, or a cell therapy;
- our beliefs regarding the potential manufacturing and distribution benefits associated with our product candidates, and our third-party CMOs' abilities to follow cGMP standards to scale up the production of our product candidates;
- our plans regarding our manufacturing facilities and our belief that our manufacturing is capable of being conducted in-house;
- our belief in the potential of our antibody-cytokine fusion proteins, DNA, RNA, or recombinant protein vaccines, or cell therapies, and the fact that our business is based upon the success individually and collectively of these platforms;
- our belief regarding the magnitude or duration for additional clinical testing of our antibody-cytokine fusion proteins, DNA, RNA or recombinant protein vaccines, or cell therapies, along with other product candidate families;
- even if we successfully develop and commercialize other specific product candidates, our ability to develop and commercialize our other product candidates either alone or in combination with other therapeutic agents;
- the ability to maintain regulatory approval of our approved product and to obtain and maintain regulatory approval of any of our other product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to successfully commercialize our approved product or any future approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain, maintain, protect, and enforce patent protection and other proprietary rights for our approved product and our other product candidates and technologies;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property relating to our product, product candidates and technology;

- our expectations regarding the results of market access initiatives and coverage under medical reimbursement policies;
- shelf life of ANKTIVA drug substance and drug product and availability of product supply;
- effectiveness of the J-code (HCPCS Level II Code) and timing thereof;
- our global expansion efforts;
- any government shutdown, which could adversely affect the U.S. and global economies, and materially and adversely affect our business and/or our future BLA submissions;
- the impact on us, if any, if the CVRs held by former Altor stockholders become due and payable in accordance with their terms; and
- regulatory developments in the U.S. and foreign countries.

Forward-looking statements include statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "continues," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "seeks," "should," "will," "would," "strategy," and variations of such words or similar expressions. and the negatives of those terms. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. These statements are based upon information available to us as of the date of this Quarterly Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

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 Part II, Item 1A. "Risk Factors" of this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report.

Except as required by law, we assume no obligation to update these forward-looking statements, 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. You should read this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect.

ImmunityBio, NantKwest, ANKTIVA, VesAnktiva, ThAnktiva, NK-92, ceNK, M-ceNK, haNK, taNK, t-haNK, GlobeImmune, Tarmogen, VivaBioCell, Nant001, NantXL, Nant Cancer Vaccine, QUILT, IPRT, Outsmart Your Disease, Smart Therapies for Difficult Diseases, and Nature's First Responder are trademarks of ImmunityBio, Inc., its subsidiaries, or its affiliates.

Our product candidates are investigational agents that are restricted by federal law to investigational use only. Safety and efficacy have not been established by any agency, including the FDA.

This Quarterly Report contains references to our trademarks and trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us, by any other companies.

In this Quarterly Report, the terms "ImmunityBio," "the company," "we," "us," and "our" refer to ImmunityBio, Inc. and its subsidiaries.

Our Business

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

Our platforms and their associated product and product candidates are designed to attack cancer and infectious pathogens by activating both the innate immune system, including—NK cells, dendritic cells, and macrophages, as well as—the adaptive immune system comprising—B and T cells—in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally-infected. Our ultimate goal is to overcome the limitations of current treatments, such as checkpoint inhibitors, and/or reduce the need for standard high-dose chemotherapy in cancer by employing this coordinated approach to establish "immunological memory" that confers long-term benefit for the patient.

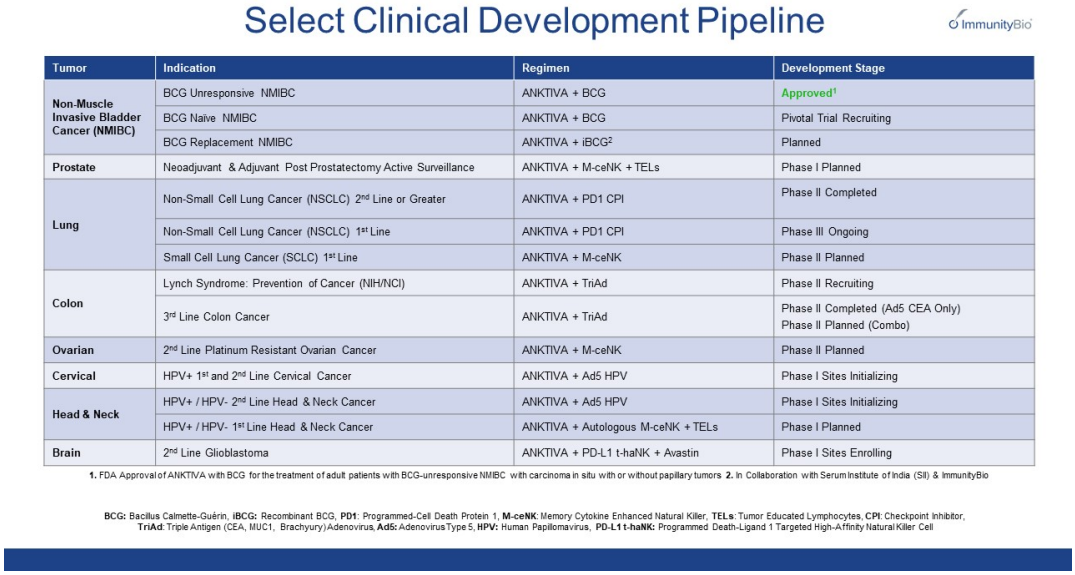
Our proprietary platforms for the development of biologic product candidates include: (i) antibody-cytokine fusion proteins, (ii) DNA, RNA, and recombinant protein vaccines, and (iii) cell therapies. As of September 2024, our platforms have generated nine first-in-human therapeutic agents (including one FDA-approved agent) that are currently or planned to be studied in clinical trials in liquid and solid tumors. Specifically, our clinical focus includes bladder, lung, and colorectal cancers and GBM, which are among the most frequent and lethal cancer types, and where there are high failure rates for existing standards of care or no available effective treatment.

Our lead biologic product ANKTIVA is a novel first-in-class IL-15 agonist antibody-cytokine fusion protein. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. Based on ANKTIVA's unique mechanism of action, we believe it has the potential to play a key role as a backbone for immunotherapy beyond T cells alone across multiple tumor types in the years to come. We began commercial distribution of our approved product in May 2024.

Further late-stage efforts for ANKTIVA are in development within the broader bladder cancer space, including BCG-naïve NMIBC. In addition, data from multiple clinical trials suggest ANKTIVA has potential to enhance the activity of therapeutic mAbs, including checkpoint inhibitors (e.g., pembrolizumab/Keytruda), across a wide range of tumor types. We believe there is potential for ANKTIVA to become a therapeutic foundation across all phases of treatment, including in adjunctive therapy, to amplify, reactivate or extend the efficacy of standard of care. In addition to ANKTIVA, we have active clinical programs evaluating therapeutic candidates from our DNA and RNA vaccine technology platforms and our NK cell-based therapy platforms in oncology and infectious disease indications.

Our Pipeline

As of September 2024, our platforms have generated nine first-in-human therapeutic agents (including one FDA-approved agent) that are currently or planned to be studied in 24 clinical trials across 17 indications in liquid and solid tumors, including bladder, lung and colorectal cancers, and GBM. These indications are among the most frequent and lethal cancer types for which there are high failure rates for existing standards of care or, in some cases, no available effective treatment. We are constantly monitoring and prioritizing clinical development based upon the availability of our resources and the efficacy and market developments of our competitors' products and product candidates, among other factors.



Tumor	Indication	Regimen	Development Stage
Non-Muscle Invasive Bladder Cancer (NMIBC)	BCG Unresponsive NMIBC	ANKTIVA + BCG	Approved[1]
	BCG Naive NMIBC	ANKTIVA + BCG	Pivotal Trial Recruiting
	BCG Replacement NMIBC	ANKTIVA + iBCG[2]	Planned
Prostate	Neoadjuvant & Adjuvant Post Prostatectomy Active Surveillance	ANKTIVA + M-ceNK + TELs	Phase I Planned
Lung	Non-Small Cell Lung Cancer (NSCLC) 2nd Line or Greater	ANKTIVA + PD1 CPI	Phase II Completed
	Non-Small Cell Lung Cancer (NSCLC) 1st Line	ANKTIVA + PD1 CPI	Phase III Ongoing
	Small Cell Lung Cancer (SCLC) 1st Line	ANKTIVA + M-ceNK	Phase II Planned
Colon	Lynch Syndrome: Prevention of Cancer (NIH/NCI)	ANKTIVA + TriAd	Phase II Recruiting
	3rd Line Colon Cancer	ANKTIVA + TriAd	Phase II Completed (Ad5 CEA Only) Phase II Planned (Combo)
Ovarian	2nd Line Platinum Resistant Ovarian Cancer	ANKTIVA + M-ceNK	Phase II Planned
Cervical	HPV+ 1st and 2nd Line Cervical Cancer	ANKTIVA + Ad5 HPV	Phase I Sites Initializing
Head & Neck	HPV+ / HPV- 2nd Line Head & Neck Cancer	ANKTIVA + Ad5 HPV	Phase I Sites Initializing
	HPV+ / HPV- 1st Line Head & Neck Cancer	ANKTIVA + Autologous M-ceNK + TELs	Phase I Planned
Brain	2nd Line Glioblastoma	ANKTIVA + PD-L1 t-haNK + Avastin	Phase I Sites Enrolling

1. FDA Approval of ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with carcinoma in situ with or without papillary tumors **2.** In Collaboration with Serum Institute of India (SII) & ImmunityBio

BCG: Bacillus Calmette-Guérin, **iBCG:** Recombinant BCG, **PD1**: Programmed-Cell Death Protein 1, **M-ceNK**: Memory Cytokine Enhanced Natural Killer, **TELs**: Tumor Educated Lymphocytes, **CPI**: Checkpoint Inhibitor, **TriAd**: Triple Antigen (CEA, MUC1, Brachyury) Adenovirus, **Ad5:** Adenovirus Type 5, **HPV:** Human Papillomavirus, **PD-L1 t-haNK:** Programmed Death-Ligand 1 Targeted High-Affinity Natural Killer Cell

Significant Developments

The following is a summary of selected significant developments affecting our business that occurred since the filing of our Quarterly Report dated June 30, 2024 with the SEC on August 12, 2024:

- ANKTIVA received a J-code (HCPCS Level II Code) in October 2024, effective January 1, 2025.
- ANKTIVA (FDA-approved and commercially available in the U.S. since May 2024) is now widely accessible to patients through commercial and government insurance programs (VA, DoD, Medicare). ImmunityBio has secured coverage for over 200 million medical lives through medical reimbursement policies.
- ImmunityBio has extended the shelf life of ANKTIVA from two years to three years, with over 125,000 doses, providing ample product for the market and for clinical trials.
- ImmunityBio submitted to the MHRA an MAA for ANKTIVA in the UK on November 1, 2024.
- ImmunityBio intends to submit to the EMA an MAA for ANKTIVA in the EU in Q4 2024, covering 30 countries, including 27 in the EU and 3 in the EEA (Iceland, Norway, Liechtenstein).

COVID-19 Pandemic

The COVID-19 pandemic continues to present a public health and economic challenge around the world. Through the date of this Quarterly Report, we have not seen a material adverse impact to our business from the pandemic. However, given the continuously evolving nature of the pandemic, we cannot at this time predict the specific extent, duration, or full impact that this pandemic may have on our financial condition and results of operations, including ongoing and planned clinical trials. More specifically, the pandemic may result in prolonged impacts that we cannot predict at this time, and we expect that such uncertainties will continue to exist for the foreseeable future.

We continue to monitor the impact of COVID-19 on our business, including our clinical trials, manufacturing facilities and capabilities, and ability to access necessary resources. For a discussion of the risks presented by the COVID-19 pandemic to our results of operations and financial condition, see Part II, Item 1A. "*Risk Factors*" of this Quarterly Report.

Operating Results

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. Now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurances when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of our other product candidates, and we do not know when, or if, this will occur.

We expect to continue to incur significant expenses as we seek to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals, increasing our manufacturing capabilities and, upon successful receipt of FDA approval, commercializing our products. Furthermore, the timing and magnitude of our approved product sales and revenue remain uncertain and may take a significant amount of time to materialize, if ever.

We have incurred net losses in each year since our inception and, as of September 30, 2024, we had an accumulated deficit of $3.3 billion. During the nine months ended September 30, 2024 and 2023, net losses attributable to ImmunityBio common stockholders were $354.4 million and $349.8 million, respectively. Substantially all of our net losses resulted principally from costs incurred in connection with our ongoing clinical trials and operations, our research and development programs, and from selling, general and administrative costs associated with our operations, including stock-based compensation expense.

As of September 30, 2024, we had 672 employees. Personnel of related companies who provide corporate, general and administrative, certain research and development, and other support services under our shared services agreement with NantWorks are not included in this number. See Note 12, *Related-Party Agreements,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for more information. In anticipation of the ongoing commercialization of our approved product, we expect to continue to incur significant expenses and increasing operating expenses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year. See "*— Future Funding Requirements*" below for a discussion of our anticipated expenditures and sources of capital we expect to access to fund these expenditures.

Collaboration Agreements

We anticipate that strategic collaborations will continue to be an integral part of our operations, providing opportunities to leverage our partners' expertise and capabilities to gain access to new technologies and further expand the potential of our technologies, approved product and product candidates across relevant platforms. We believe we are well positioned to become a leader in immunotherapy due to our broad and vertically-integrated platforms and through complementary strategic partnerships.

We believe that our innovative approach to orchestrate and combine therapies for optimal immune system response will become a therapeutic foundation across multiple indications. Additionally, we believe that data from multiple clinical trials indicates ANKTIVA has broad potential to enhance the activity of therapeutic mAbs, including checkpoint inhibitors, across a wide range of tumor types. We may also enter into supply arrangements for various investigational agents to be used in our clinical trials. See Part I, Item 1. "*Business—Collaboration and License Agreements*" of our Annual Report filed with the SEC on March 19, 2024 for a more detailed discussion regarding our collaboration and license agreements.

Agreements with Related Parties

Our Executive Chairman and Global Chief Scientific and Medical Officer founded and has a controlling interest in NantWorks, which is a collection of companies in the healthcare and technology space. We have entered into arrangements with NantWorks, and certain affiliates of NantWorks. Affiliates of NantWorks are also affiliates of the company due to the common control by and/or common ownership interest of our Founder, Executive Chairman and Global Chief Scientific and Medical Officer.

Related-Party Debt

See Note 11, *Related-Party Debt,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for information regarding our related-party debt.

Immuno-Oncology Clinic, Inc.

We have entered into multiple agreements with the Clinic to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by an officer of the company and NantWorks manages the administrative operations of the Clinic.

In 2021, we completed a review of alternative structures that could support our more complex clinical trial requirements and made a decision to explore a potential transition of clinical trials at the Clinic to a new structure (including contracting with a new, non-affiliated professional corporation) to be determined and agreed upon by all parties. While we have not yet finalized the potential transaction, we continue discussions with potential partners around alternative structures. During the nine months ended September 30, 2024 and 2023, we incurred $2.1 million and $1.9 million, respectively, in *research and development expense*, on the condensed consolidated statements of operations related to clinical trial and transition services provided by the Clinic.

See Note 12, *Related-Party Agreements*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for more information regarding our related-party agreements.

Components of our Results of Operations

Revenue

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. Now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurances when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of our other product candidates, and we do not know when, or if, this will occur.

Operating Expenses

We generally classify our operating expenses into cost of product revenue, research and development, and selling, general and administrative expenses. Personnel costs, including salaries, benefits, bonuses, and stock-based compensation expense comprise a significant component of our research and development, and selling, general and administrative expense categories. We allocate expenses associated with our facilities and information technology costs between these two categories, primarily based on the nature of each cost.

Cost of Product Revenue

Cost of product revenue consists primarily of third-party manufacturing costs, distribution, and overhead costs related to ANKTIVA sales. Cost of product revenue may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the condensed consolidated statement of operations in the period incurred and therefore are not reflected in cost of product revenue.

Research and Development

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our technology and product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory submissions for product candidates. We recognize research and development expenses as they are incurred.

Our research and development expenses primarily consist of:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with investigative sites and consultants that conduct our clinical trials;
- expenses incurred under collaborative agreements;
- manufacturing and testing costs and related supplies and materials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation; and
- facility expenses dedicated to research and development.

The company classifies its research and development expenses as either external or internal. The company's external research and development expenses support its various preclinical and clinical programs. The company's internal research and development expenses include payroll and benefits expenses, facilities and equipment expense, and other indirect research and development expenses incurred in support of its research and development activities. The company's external and internal resources are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs and are not allocated to specific product candidates or development programs.

We expect our research and development expenses to increase significantly for the foreseeable future as we continue to invest in research and development activities related to expanding our product into new indications and markets, developing our other product candidates, and conducting our ongoing and planned clinical trials.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our other product candidates or to expand potential approved indications for ANKTIVA. This is due to the numerous risks and uncertainties associated with the development of product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses that patients receive;
- the cost of comparative agents used in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the safety profile and efficacy of the product candidate.

We have only one approved product, ANKTIVA, for which we received approval from the FDA on April 22, 2024. We began commercial distribution of our approved product in May 2024. There can be no assurance that our other product candidates will be approved for commercial sale by the FDA in the near term, if ever. We do not expect any of our other product candidates to be commercially available in the foreseeable future, if ever.

Selling, General and Administrative

Selling, general and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in executive, finance, human resources, information technology, legal, sales and administrative support functions. Other selling, general and administrative expenses include sales and marketing costs, facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, advertising costs, expenses associated with strategic business transactions and business development efforts, obtaining and maintaining patents, consulting costs, royalties and licensing costs, and costs of our information systems.

We expect that our selling, general and administrative expense will increase for the foreseeable future as we commercialize our approved product, and expand operations, build out information systems and increase our headcount to support continued research activities and the development of our clinical programs. We have incurred and expect that we will continue to incur in the future, additional costs associated with operating as a public company, including costs to comply with stock exchange listing and SEC requirements, future funding efforts, corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public companies. Additionally, if and when we believe that a regulatory approval of one of our other product candidates appears likely, we expect to incur significant increases in our selling, general and administrative expense relating to the sales and marketing of any additional approved product candidate.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest and investment income, interest expense (including amortization of debt discounts), unrealized gains and losses from investments in equity securities and equity-method investments, changes in fair value of warrants, derivative liabilities, and a convertible note, realized gains and losses on debt and equity securities, and gains and losses on foreign currency transactions.

Income Taxes

We are subject to U.S. federal income tax, as well as income tax in Italy, South Korea, California and other states. From inception through September 30, 2024, we have not been required to pay U.S. federal and state income taxes because of current and accumulated NOLs.

Discussion of Condensed Consolidated Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

	Three Months Ended September 30,			
	2024	2023	$ Change	% Change
	(Unaudited, $ in thousands)			
Revenue				
Product revenue, net	$ 5,954	$ —	$ 5,954	— %
Other revenues	152	82	70	85 %
Total revenue	6,106	82	6,024	7346 %
Operating costs and expenses:				
Cost of product revenue	—	—	—	— %
Research and development (including amounts with related parties)	50,443	48,402	2,041	4 %
Selling, general and administrative (including amounts with related parties)	35,916	31,816	4,100	13 %
Total operating costs and expenses	86,359	80,218	6,141	8 %
Loss from operations	(80,253)	(80,136)	(117)	— %
Other income (expense), net				
Interest and investment income (loss), net	1,798	35	1,763	5037 %
Change in fair value of warrant liabilities	31,324	14,265	17,059	120 %
Interest expense (including amounts with related parties)	(29,322)	(35,021)	5,699	(16)%
Interest expense related to revenue interest liability	(10,925)	—	(10,925)	— %
Change in fair value of derivative liabilities	1,614	—	1,614	— %
Change in fair value of related-party convertible note	—	7,517	(7,517)	(100)%
Loss on equity method investment	—	(1,255)	1,255	(100)%
Other income (expense), net (including amounts with related parties)	12	(1,047)	1,059	(101)%
Total other expense, net	(5,499)	(15,506)	10,007	(65)%
Loss before income taxes and noncontrolling interests	(85,752)	(95,642)	9,890	(10)%
Income tax expense	—	—	—	— %
Net loss	$ (85,752)	$ (95,642)	$ 9,890	(10)%

Product Revenue, Net

Product revenue, net increased $6.0 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023, due to sales of ANKTIVA, which was approved in April 2024.

Other Revenues

Other revenues increased $0.1 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023, driven by higher bioreactor and related consumable product sales over the prior period.

Cost of Product Revenue

We did not report cost of product revenue during the three months ended September 30, 2024. Cost of product revenue consists primarily of third-party manufacturing, distribution and overhead costs. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the condensed consolidated statement of operations in the period incurred and therefore are not reflected in cost of product revenue. As a result, our initial product gross margin is higher as our pre-launch inventory costs are not included in the cost of product revenue. We expect the cost of product revenue for ANKTIVA to increase in relation to product revenues as we deplete these inventories.

Research and Development Expense

Research and development expense increased $2.0 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. The following table summarizes our research and development expenses during the three months ended September 30, 2024 and 2023, together with the changes in those items (in thousands):

	Three Months Ended September 30,		
	2024	2023	$ Change
	(Unaudited)		
External research and development expenses	$ 8,114	$ 12,580	$ (4,466)
Internal research and development expenses:			
Personnel-related costs	22,712	18,396	4,316
Equipment, depreciation, and facility costs	13,223	13,250	(27)
Other research and development costs	6,394	4,176	2,218
Total internal research and development expenses	42,329	35,822	6,507
Total research and development expenses	$ 50,443	$ 48,402	$ 2,041

Research and development expense increased $2.0 million primarily attributable to the following:

- a $4.5 million decrease in external research and development expenses, primarily due to a reduction in outside services, lower CMO fees and fewer drug materials purchased and used in manufacturing, partially offset by higher clinical trial activities; offset by
- a $4.3 million increase in personnel-related costs, primarily due to an increase in bonus and termination benefits, partially offset by lower stock-based compensation expense and shared service costs compared to the prior period; and
- a $2.2 million increase in other research and development costs, primarily due to a credit allocated to a joint venture in the prior period that is not expected to recur, a gain recognized from the termination of a lease used for R&D in the prior period, and higher lab supplies and distribution costs.

We expect our research and development expenses to increase significantly for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates and conducting our ongoing and planned clinical trials.

Selling, General and Administrative Expense

Selling, general and administrative expense increased $4.1 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. The increase in selling, general and administrative expense was primarily driven by a $5.3 million increase in salary and benefits expenses, primarily due to the reversal of accrued discretionary bonuses for 2022 not paid and a reduction in headcount during the three months ended September 30, 2023, an increase of $4.9 million in consulting costs, primarily associated with commercial activities, an increase of $0.6 million in equipment, depreciation and facility costs, an increase of $0.5 million in recruiting fees, an increase of $0.4 million in travel expenses, and an increase of $0.3 million in license fees. The increase in selling, general and administrative expense was partially offset by a $4.3 million decrease in legal expenses and a $3.6 million decrease in stock-based compensation expense.

Other Income (Expense), Net

Other expense, net decreased $10.0 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. The decrease in other expense, net was primarily driven by a decrease of $17.1 million due to the change in fair value of warrant liabilities, a decrease of $5.7 million in interest expense, a $1.8 million increase in interest and investment income primarily resulting from accretion income on our marketable debt securities, a decrease of $1.6 million due to the change in fair value of derivative liabilities, and a $1.0 million decrease in other expenses, net. The decrease in other expense, net was partially offset by an increase of $10.9 million from interest expense related to the revenue interest liability, and an increase of $6.3 million due to the change in fair value of a related-party convertible note and a loss in an equity method investment recorded during the prior period.

Comparison of the Nine Months Ended September 30, 2024 and 2023

	Nine Months Ended September 30,			
	2024	2023	$ Change	% Change
	(Unaudited, $ in thousands)			
Revenue				
Product revenue, net	$ 6,944	$ —	$ 6,944	— %
Other revenues	249	483	(234)	(48)%
Total revenue	7,193	483	6,710	1389 %
Operating costs and expenses				
Cost of product revenue	—	—	—	— %
Research and development (including amounts with related parties)	154,923	180,834	(25,911)	(14)%
Selling, general and administrative (including amounts with related parties)	127,052	96,510	30,542	32 %
Total operating costs and expenses	281,975	277,344	4,631	2 %
Loss from operations	(274,782)	(276,861)	2,079	(1)%
Other income (expense), net				
Interest and investment income, net	6,788	647	6,141	949 %
Interest expense (including amounts with related parties)	(88,599)	(97,072)	8,473	(9)%
Interest expense related to revenue interest liability	(28,154)	—	(28,154)	— %
Change in fair value of derivative liabilities	20,084	—	20,084	— %
Change in fair value of warrant liabilities	10,222	31,800	(21,578)	(68)%
Change in fair value of related-party convertible note	—	749	(749)	(100)%
Loss on equity method investment	—	(7,549)	7,549	(100)%
Other expense, net (including amounts with related parties)	(25)	(2,152)	2,127	(99)%
Total other expense, net	(79,684)	(73,577)	(6,107)	8 %
Loss before income taxes and noncontrolling interests	(354,466)	(350,438)	(4,028)	1 %
Income tax expense	—	—	—	— %
Net loss	$ (354,466)	$ (350,438)	$ (4,028)	1 %

Product Revenue, Net

Product revenue, net increased $6.9 million during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. The increase was driven by sales of ANKTIVA after FDA approval in April 2024.

Other Revenues

Other revenues decreased $0.2 million during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023 as a result of a decline in grant revenue.

Cost of Product Revenue

We did not report cost of product revenue during the nine months ended September 30, 2024. Cost of product revenue consists primarily of third-party manufacturing, distribution and overhead costs. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense* , on the condensed consolidated statement of operations in the period incurred and therefore are not reflected in cost of product revenue. As a result, our initial product gross margin is higher as our pre-launch inventory costs are not included in the cost of product revenue. We expect the cost of product revenue for ANKTIVA to increase in relation to product revenues as we deplete these inventories.

Research and Development Expense

Research and development expense decreased $25.9 million during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. The following table summarizes our research and development expenses during the nine months ended September 30, 2024 and 2023, together with the changes in those items (in thousands):

	Nine Months Ended September 30,		
	2024	2023	$ Change
	(Unaudited, $ in thousands)		
External research and development expenses	$ 27,575	$ 58,413	$ (30,838)
Internal research and development expenses:			
Personnel-related costs	69,765	65,966	3,799
Equipment, depreciation, and facility costs	39,279	39,588	(309)
Other research and development costs	18,304	16,867	1,437
Total internal research and development expenses	127,348	122,421	4,927
Total research and development expenses	$ 154,923	$ 180,834	$ (25,911)

Research and development expense decreased $25.9 million primarily attributable to the following:

- a $30.8 million decrease in external research and development expenses that was primarily due to a reduction in CMO fees and drug materials purchased and used in manufacturing, a reduction in clinical trial costs, and a reduction in outside services costs; partially offset by
- a $3.8 million increase in personnel-related costs that was primarily due to an increase in salary and benefits expense from the write off of accrued discretionary bonuses for 2022 not paid and a reduction in headcount during the nine months ended September 30, 2023, partially offset by a decrease in stock-based compensation costs due to decreases in headcount during the nine months ended September 30, 2024;
- a $0.3 million decrease in equipment, depreciation, and facility costs that was primarily due to a decrease in lease expense due to the termination of a lease used for R&D in the prior period and a decrease in depreciation expense due to fully depreciated assets, partially offset by increased facility costs; and partially offset by
- a $1.4 million increase in other research and development costs, primarily attributable to no costs allocated to a joint venture and higher research agreements cost due to new agreements, partially offset by lower manufacturing cost due to decreased production activities.

We expect our research and development expenses to increase significantly for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates and conduct our ongoing and planned clinical trials.

Selling, General and Administrative Expense

Selling, general and administrative expense increased $30.5 million during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. The increase in selling, general and administrative expense was primarily driven by an increase of $16.9 million in legal expenses, driven by higher defense costs and increased general legal services, an increase of $12.2 million in consulting costs, primarily associated with commercial readiness activities, a $7.0 million increase in salary and benefits expenses primarily due to the reversal of accrued discretionary bonuses for 2022 not paid and a reduction in headcount during the nine months ended September 30, 2023, a $0.9 million increase in license fees, and a $0.7 million increase in marketing expenses, partially offset by a $7.2 million reduction in stock-based compensation expense.

Other Income (Expense), Net

Other expense, net increased $6.1 million during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. The increase in other expense, net was primarily driven by an increase of $28.2 million of interest expense related to the revenue interest liability, an increase of $21.6 million due to the change in fair value of warrant liabilities, and a $0.7 million decrease from a gain in the fair value of a related-party convertible note recorded during the prior period. These increases were partially offset by a decrease of $20.1 million due to the change in fair value of derivative liabilities, a decrease of $8.5 million in interest expense (including amounts with related parties), a decrease of $7.5 million due to loss on equity method investments recorded during the prior period, an increase of $6.1 million in interest and investment income, net, and a decrease of $2.2 million in other expense, net (including amounts with related parties).

Financial Condition, Liquidity and Capital Resources

Sources of Liquidity

From inception through September 30, 2024, we have funded our operations primarily through proceeds from the issuance of related-party promissory notes, sales of our common stock, our shelf registration statements and through RDOs, and a RIPA financing.

Cash and Marketable Securities on Hand

As of September 30, 2024, we had cash and cash equivalents, and marketable securities of $130.4 million compared to $267.4 million as of December 31, 2023. We have typically invested our cash in a variety of financial instruments and classified these investments as available-for-sale. However, after our entry into the RIPA we can no longer invest our excess funds in corporate or European bonds. Certain of our investments are subject to credit, liquidity, market, and interest-rate risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets.

Open Market Sale Agreement

In April 2024, we filed a shelf registration statement and associated prospectus that increased the amount available under the ATM to $300.8 million. As of September 30, 2024, we had $296.5 million available for future stock issuances under the ATM.

Shelf Registration Statements

During February 2023, we filed a $750.0 million shelf registration statement with the SEC on Form S-3 for the offering and sale of equity and equity-linked securities, including common stock, preferred stock, debt securities, depositary shares, warrants to purchase common stock, preferred stock or debt securities, subscription rights, purchase contracts, and units. As of September 30, 2024, we had $565.6 million available for use under the shelf.

During April 2024, we filed a shelf registration statement with the SEC on Form S-3 pursuant to which we may, from time to time, sell an indeterminate amount of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units, and an associated prospectus related to the ATM.

Amounts available for use as of September 30, 2024 under these shelf registration statements are in addition to the amount available under the ATM described above.

Exercise of Warrants

During the nine months ended September 30, 2024, 22,242,740 of the February and July 2023 Warrants were exercised from which we received proceeds of $73.3 million. As of September 30, 2024, a total of 15,490,080 warrants remained outstanding at exercise prices ranging from $3.2946 per share to $6.60 per share.

During the three months ended September 30, 2024, institutional holders exercised a total of 4,740,249 warrants pursuant to the February 2023 Warrant agreement at an exercise price of $3.2946 per share resulting in the issuance of 4,740,249 shares of the company's common stock for proceeds totaling $15.6 million.

Revenue Interest Purchase Agreement

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain initial Revenue Interests from us for a gross purchase price of $200.0 million paid on closing, less certain issuance costs. Oberland had the option to purchase additional Revenue Interests from us in exchange for a $100.0 million Second Payment upon satisfaction of certain conditions in the RIPA, including receipt of approval by the FDA of our BLA for ANKTIVA on or before June 30, 2024.

On April 22, 2024, the FDA approved our product ANKTIVA and as a result, on May 13, 2024 Oberland purchased additional Revenue Interests from us for a gross purchase price of $100.0 million, less certain issuance costs.

As consideration for the aforementioned payments, Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, a certain percentage of our net sales during such quarter, which are tiered payments ranging from 4.5% to 10.0% (before funding of the Second Payment, 3.0% to 7.0%) of the company's worldwide net sales, excluding those in China. See Note 10, *Revenue Interest Purchase Agreement*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for more information.

Stock Purchase and Option Agreement

On December 29, 2023 and in connection with the RIPA, we entered into an SPOA with Oberland. Under this agreement, Oberland had an option to purchase up to $10.0 million of our common stock, at a price per share to be determined by reference to the 30-day trailing volume weighted-average price of our common stock, calculated from the date of exercise. The option is exercisable by Oberland at any time until the earliest of (i) December 29, 2028, (ii) a change of control of the company, or (iii) a sale of substantially all of the company's assets. Among other limitations, the option may only be exercised to the extent that the common stock issuable pursuant to such exercise would not exceed 19.9% of the common stock outstanding immediately after giving effect to such exercise.

Pursuant to the SPOA, in April 2024 Oberland exercised part of their option and purchased 858,990 shares of our common stock at an exercise price of $5.8208 per share generating net proceeds of approximately $4.9 million. Following such exercise, approximately $5.0 million remains available for future exercise under the SPOA as of September 30, 2024.

Uses of Liquidity

In addition to the cash used to fund our operating activities discussed in " *—Future Funding Requirements*" below, we will require cash to settle the following obligations:

- As of September 30, 2024, our indebtedness payable at maturity totals $735.0 million (excluding unamortized related-party notes discounts and fair value adjustments), held by entities affiliated with Dr. Soon-Shiong. In connection with the RIPA, all of our related-party promissory notes are now general unsecured obligations of the company that are subordinated in right of payment to indebtedness, obligations and other liabilities under the RIPA, the Revenue Interests issued pursuant to such agreement, and refinancing of the foregoing. In addition, the terms of promissory notes totaling $535.0 million were amended and restated to extend the maturity date by one year to December 31, 2025. The remaining $200.0 million promissory note and any accrued and unpaid interest are due on the earlier of (i) September 11, 2026 or (ii) upon the occurrence and during the continuance of an event of default (as defined in the note).
    - Pursuant to the terms of the amended and restated promissory note, the amended $505.0 million December 2023 promissory note is comprised of the Tranche 1 principal amount of $125.0 million and the Tranche 2 principal amount of $380.0 million. All of the Tranche 2 principal amount of $380.0 million and any accrued and unpaid interest can be converted into shares of the company's stock at $8.2690 per share at the option of the noteholder. The interest rates for the Tranche 1 principal amount and Tranche 2 principal amount of the $505.0 million December 2023 promissory note were Term SOFR plus 8.0% per annum and Term SOFR plus 7.5% per annum, respectively.
    - The $200.0 million convertible promissory note bears interest at Term SOFR plus 8.0% per annum. The noteholder has the sole option to convert all of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $1.9350 per share.
    - The $30.0 million convertible promissory note bears interest at Term SOFR plus 8.0% per annum. The noteholder has the sole option to convert all of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $2.28 per share.

  There can be no assurance that the company can refinance these promissory notes or what terms will be available in the market at the time of refinancing. Furthermore, if prevailing interest rates or other factors at the time of refinancing result in higher interest rates upon refinancing, then the interest expense relating to the refinanced indebtedness would increase. These risks could materially adversely affect the company's financial condition, cash flows and results of operations.
- On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, our worldwide net sales, excluding those in China, which are tiered payments ranging from 4.5% to 10.0% (before funding of the Second Payment, 3.0% to 7.0%), subject to increase or decrease, following December 31, 2029 (the Test Date) depending on whether our aggregate payments made to Oberland as of the Test Date have met or exceeded the Cumulative Purchaser Payments. In addition, if our aggregate payments made as of the Test Date to Oberland do not equal or exceed the amount of the Cumulative Purchaser Payments as of such date, then we are obligated to make a one-time True-Up Payment to Oberland in an amount equal to 100% of the Cumulative Purchaser Payments as of the Test Date, less the aggregate amount of our previous payments to Oberland as of the Test Date. See Note 10, *Revenue Interest Purchase Agreement*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for more information regarding the RIPA.
- In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026, with amounts payable in cash or shares of our common stock or a combination thereof. As of September 30, 2024, Dr. Soon-Shiong and his related party hold approximately $139.8 million of net sales CVRs and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. We may be required to pay the other prior Altor stockholders up to $164.2 million for their net sales CVRs should they choose to have their CVRs paid in cash instead of common stock. We may need to seek additional sources of capital to satisfy the CVR obligations if they are achieved.

- In connection with our acquisition of VivaBioCell, we are obligated to pay the former owners approximately $2.2 million of contingent consideration upon the achievement of a regulatory milestone relating to the GMP-in-a-Box technology.

Discussion of Condensed Consolidated Cash Flows

The following discussion of ImmunityBio's cash flows is based on the condensed consolidated statements of cash flows in Item 1. "Financial Statements" and is not meant to be an all-inclusive discussion of the changes in its cash flows for the periods presented below.

The following table sets forth our primary sources and uses of cash for periods indicated (in thousands):

	Nine Months Ended September 30,	
	2024	2023
	(Unaudited)	
Cash (used in) provided by:		
Operating activities	$ (306,092)	$ (251,486)
Investing activities	(22,080)	(32,719)
Financing activities	174,701	357,802
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	(16)	(265)
Net change in cash and cash equivalents, and restricted cash	$ (153,487)	$ 73,332

Operating Activities

During the nine months ended September 30, 2024, net cash used in operating activities of $306.1 million consisted of a net loss of $354.5 million and $8.5 million of cash used in net working capital, partially offset by $56.9 million in adjustments for non-cash items. The changes in net working capital consisted primarily of an increase of $4.2 million in accounts receivable, net, a decrease of $3.9 million in operating lease liabilities, an increase of $2.0 million in inventories and an increase of $0.1 million in other assets, partially offset by an increase of $0.7 million in accounts payable and accrued expenses and other liabilities, an increase of $0.6 million with related parties, and a decrease of $0.4 million in prepaid expenses and other current assets. Adjustments for non-cash items primarily consisted of $27.7 million of non-cash interest expense related to the revenue interest liability, $25.4 million in stock-based compensation expense, $17.6 million in amortization of related-party note discounts, $13.4 million in depreciation and amortization expense, $4.1 million in non-cash lease expense related to operating lease right-of-use assets, and $0.5 million in unrealized losses on equity securities driven by a decrease in the value of our investments, reduced by a $20.1 million change in the fair value of derivative liabilities, a $10.2 million change in the fair value of warrant liabilities, and $1.5 million of accretion of discounts on marketable debt securities.

During the nine months ended September 30, 2023, net cash used in operating activities of $251.5 million consisted of a net loss of $350.4 million, partially offset by $69.2 million in adjustments for non-cash items and $29.7 million of cash provided by net working capital. Adjustments for non-cash items primarily consisted of $36.4 million in stock-based compensation expense, $35.3 million in amortization of related-party note discounts, $13.9 million in depreciation and amortization expense, $9.0 million in non-cash interest primarily related to related-party promissory notes, $4.8 million in non-cash lease expense related to operating lease right-of-use assets, $2.0 million in transaction costs allocable to warrant liabilities, and $0.9 million in unrealized losses on equity securities driven by a decrease in the value of our investments, reduced by a $31.8 million change in the fair value of warrant liabilities, a $0.7 million change in the fair value of a related-party convertible note, and $0.6 million in other non-cash items. The changes in net working capital consisted primarily of an increase of $26.2 million in accrued expenses and other liabilities, a decrease of $9.5 million in prepaid and other current assets, and a decrease of $1.3 million in other assets, partially offset by decreases of $3.6 million in accounts payable, $2.4 million in operating lease liabilities, and $1.3 million with related parties.

We have historically experienced negative cash flows from operating activities, with such negative cash flows likely to continue for the foreseeable future.

Investing Activities

During the nine months ended September 30, 2024, net cash used in investing activities was $22.1 million, which included cash outflows of $134.1 million of purchases of marketable debt securities, $4.8 million of purchases of property, plant and equipment, $1.0 million used for the acquisition of a business, net of transaction costs, and $0.7 million cash paid for other investments, partially offset by proceeds of $118.5 million from maturities and sales of marketable debt securities.

During the nine months ended September 30, 2023, net cash used in investing activities was $32.7 million, which included cash outflows of $22.6 million of purchases of property, plant and equipment, and $10.2 million of purchases of marketable debt securities, partially offset by proceeds of $0.1 million from maturities and sales of marketable debt and equity securities.

Our investments in property, plant and equipment are primarily related to acquisitions of equipment that will be used for the manufacturing of our approved product and product candidates and expenditures related to the build out of our manufacturing facilities. We expect to accelerate our capital spending as we scale our GMP manufacturing capabilities, which will require significant capital for the foreseeable future.

Financing Activities

During the nine months ended September 30, 2024, net cash provided by financing activities was $174.7 million, which consisted of $97.0 million in net proceeds from payments received pursuant to the RIPA, $73.3 million of proceeds from the exercise of warrants, $4.9 million in net proceeds from the partial exercise of the Oberland stock option, $3.6 million in net proceeds from equity offerings, and $0.7 million in proceeds from the exercise of stock options, partially offset by $4.7 million related to net share settlement of vested RSUs for payment of payroll tax withholding and $0.1 million in principal payments of finance leases.

During the nine months ended September 30, 2023, net cash provided by financing activities was $357.8 million, which consisted of $258.7 million in net proceeds from issuances of related-party promissory notes, $100.7 million in net proceeds from equity offerings, and $0.3 million in proceeds from the exercise of stock options, partially offset by $1.9 million related to net share settlement of vested RSUs for payment of payroll tax withholding.

Future Funding Requirements

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. Now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurances when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of our other product candidates, and we do not know when, or if, this will occur. In addition, we expect our operating expenses to significantly increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our other product candidates. We have also incurred and expect that we will continue to incur in the future additional costs associated with operating as a public company as well as costs related to future fundraising efforts. In addition, subject to obtaining regulatory approval of our other product candidates, we expect to incur significant incremental commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our operating expenses will increase substantially if and as we:

- commercialize our approved product;
- continue research and development, including preclinical and clinical development of our other existing product candidates;
- potentially seek regulatory approval for our other current product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our other product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates' development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

As a result of continuing anticipated operating cash outflows as we commercialize our approved product and accelerate our development efforts, we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support. However, we believe our existing cash and cash equivalents, and investments in marketable securities; sales of our approved product; capital to be raised through equity offerings, including but not limited to, the offering, issuance and sale by us of our common stock under the ATM, of which we had $296.5 million available for future issuance as of September 30, 2024; and our potential ability to borrow from affiliated entities will be sufficient to fund our operations through at least the next 12 months following the issuance date of the consolidated financial statements based primarily upon our Founder, Executive Chairman and Global Chief Scientific and Medical Officer's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt. In addition to funds from the future sales of our approved product, which we expect to take time to establish, we may also seek to sell additional equity, through one or more follow-on public offerings, or in separate financings, or obtain a credit facility, issue other debt in compliance with the terms of the RIPA, or engage in strategic partnership transactions. However, we may not be able to secure such external financing in a timely manner or on favorable terms, if at all. Without additional funds, we may choose to delay or reduce our operating or investment expenditures. Further, because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we may need additional funds to meet our needs sooner than planned.

We will need to obtain additional financing to fund our future operations, including completing the commercialization of our approved product and the development and commercialization of our other product candidates. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate and we may need to raise additional funds sooner than we presently anticipate. Moreover, research and development and our operating costs and fixed expenses such as rent and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

Our future funding requirements will depend on many factors, including, but not limited to:

- our ability and the time required to successfully commercialize our approved product;
- progress, timing, number, scope and costs of researching and developing our product candidates and our ongoing, planned and potential clinical trials;
- time and cost of regulatory approvals;
- our ability to successfully commercialize any of our other product candidates, if approved and the costs of such commercialization activities;

- revenue from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- interest and principal payments on our related-party promissory notes, and repayment of Revenue Interests and Test Date payments due under the RIPA;
- cost of building, staffing and validating our own manufacturing facilities in the U.S., including having a product candidate successfully manufactured consistent with FDA and EMA regulations;
- terms, timing and costs of our current and any potential future collaborations, business or product acquisitions, CVRs, milestones, royalties, licensing or other arrangements that we have established or may establish;
- time and cost necessary to respond to technological, regulatory, political and market developments; and
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights.

Unless and until we can generate a sufficient amount of revenues, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all, including but not limited to the offering, issuance and sale by us of our common stock that may be issued and sold under the ATM.

To the extent that we raise additional capital through the sale of equity or equity-linked securities (including warrants), convertible debt or through the ATM, our shelf registration statements, or other offerings, or if any of our current debt is converted into equity or if our existing warrants are exercised, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Contractual Obligations

We have material cash requirements to pay related-party affiliates and third parties under various contractual obligations discussed below:

- We are obligated to make payments to several related-party affiliates under written agreements and other informal arrangements. We are also obligated to pay interest and to repay principal under our related-party promissory notes. See Note 11, *Related-Party Debt,* of the “Notes to Unaudited Condensed Consolidated Financial Statements” that appears in Item 1. “Financial Statements” of this Quarterly Report for information regarding our financing obligations.
- We are obligated to make payments to Oberland associated with our revenue interest liability, which do not have a fixed repayment schedule. Oberland’s right to receive payments under the RIPA shall terminate when Oberland has received maximum payments (including any True-Up Payment) equal to 195.0% of the then Cumulative Purchaser Payments unless the RIPA is terminated prior to such date.

Under the terms of the agreement, prior to the Test Date, every $100.0 million of worldwide net sales, excluding those in China, of less than or equal to $600.0 million in a calendar year will result in a tiered Revenue Interest Payment of approximately $10.0 million or 10.0% (after funding of the Second Payment). Worldwide net sales, excluding those in China, for a calendar year exceeding $600.0 million will result in a tiered Revenue Interest Payment of approximately $4.5 million or 4.5% (after funding of the Second Payment) for every $100.0 million of worldwide net sales, excluding those in China, above the threshold.

In the future, cumulative worldwide net sales, excluding those in China, levels up to the Test Date will determine whether or not we are required to make a True-Up Payment and implement modified payment rates. The amount of the obligation and timing of payment is likely to change. See Note 10, *Revenue Interest Purchase Agreement,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for more information regarding the RIPA.

- We are obligated to make payments under our operating leases, which primarily consist of facility leases. See Note 9, *Lease Arrangements,* and Note 12, *Related-Party Agreements,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appear in Item 1. "Financial Statements" of this Quarterly Report for information regarding our lease obligations.
- In connection with the acquisitions of Altor and VivaBioCell, we are obligated to pay contingent consideration upon the achievement of certain milestones. See Note 8, *Commitments and Contingencies—Contingent Consideration Related to Business Combinations,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for information regarding our contingent consideration obligations.
- We have contractual obligations to make payments to related-party affiliates and third parties under unconditional purchase arrangements. See Note 7, *Commitments and Contingencies—Unconditional Purchase Obligations,* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of our Annual Report filed with the SEC on March 19, 2024 for information on these unconditional purchase obligations.
- We have certain contractual commitments that are expected to be paid within one year, depending on the progress of build outs, completion of services, and the realization of milestones associated with third-party agreements. This amount totals $34.6 million and is primarily related to capital expenditures and open purchase orders as of September 30, 2024 for the acquisition of goods and services in the ordinary course of business, and near-term upfront milestone payments to third parties.
- In addition, we have contractual commitments that are expected to be paid in fiscal year 2025 and beyond based on the achievement of various development, regulatory and commercial milestones for agreements with third parties. These payments may not be realized or may be modified and are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. As of September 30, 2024, the maximum amount that may be payable related to these commitments is $432.5 million.
- In connection with our leasehold interest in the Dunkirk Facility, we committed to spend an aggregate of $1.52 billion on operational expenses during the initial 10-year term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. These amounts are not included in the discussion above. See Note 7, *Collaboration and License Agreements and Acquisition—Acquisition* , of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report for more information on these obligations.

Critical Accounting Policies and Estimates

In Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report filed with the SEC on March 19, 2024, we disclose those accounting policies that we consider to be significant in determining our results of operations and financial condition. There have been no material changes to those policies that we consider to be significant as of the date of this Quarterly Report, except as updated in Note 2, *Summary of Significant Accounting Policies* , of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report as it relates to revenue recognition, cost of product revenue, accounts receivable, inventory, warrants, convertible notes, debt, revenue interest liability, and derivative liabilities.

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of condensed consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to the valuation of equity-based awards, deferred income taxes and related valuation allowances, revenue interest liability, preclinical and clinical trial accruals, impairment assessments, CVR measurement and assessments, the measurement of right-of-use assets and lease liabilities, useful lives of long-lived assets, loss contingencies, fair value calculation of warrants and convertible promissory notes, fair value measurements, asset acquisition, and the assessment of our ability to fund our operations for at least the next 12 months from the date of issuance of these condensed consolidated financial statements. We base our estimates on historical experience and on various other market-specific and relevant assumptions that we believe to be reasonable under the circumstances. Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that any ongoing pandemic could have on our significant accounting estimates. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Refer to Note 2, *Summary of Significant Accounting Policies* , of the “Notes to Unaudited Condensed Consolidated Financial Statements” that appears in Item 1. “Financial Statements” of this Quarterly Report for a discussion of recent accounting pronouncements or changes in accounting pronouncements that are of significance, or potential significance, to us.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Financial market risks related to interest rates, foreign currency exchange rates, market risk on the price and volatility of our common stock, and inflation are described in Part II, Item 7A. “Quantitative and Qualitative Disclosures About Market Risk” of our Annual Report filed with the SEC on March 19, 2024. There have been no material changes to such financial market risks as of the date of this Quarterly Report. We do not currently anticipate any other near-term changes in the nature of our financial market risk exposures or in management’s objectives and strategies with respect to managing such exposures.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. There is no assurance that our disclosure controls and procedures will operate effectively under all circumstances.

Management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term “disclosure controls and procedures,” as defined in Rule 13a-15(e) of the Exchange Act means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our CEO and CFO have concluded that, as of September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

In May 2024, we began shipping and recording revenue and inventory related to ANKTIVA. In addition, we are using a third-party logistics provider for shipping, finished goods inventory management, customer service, and certain other logistical and financial reporting services related to these shipments of ANKTIVA. As a result, we are relying on their systems and processes for the above functions. We have implemented a variety of internal control processes in various functional areas of our company to ensure that financial data related to ANKTIVA revenue and inventory activity has been correctly reflected in our condensed consolidated financial statements. Additionally, we also evaluated the adequacy and effectiveness of the internal controls at our third-party logistics provider. We are not aware of any material adverse impacts on our internal control over financial reporting as a result of the implementation of these new controls.

There have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fiscal quarter ended September 30, 2024, that our certifying officers concluded materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. If we are served with any such complaints, we will assess at that time any contingencies for which we may need to reserve. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Shenzhen Beike Biotechnology Co. Ltd. Arbitration

In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration. The arbitration relates to a license, development, and commercialization agreement that Altor entered into with Beike in 2014, which agreement was amended and restated in 2017, pursuant to which Altor granted to Beike an exclusive license to use, research, develop and commercialize products based on ANKTIVA in China for human therapeutic uses. In the arbitration, Beike is asserting a claim for breach of contract under the license agreement. Among other things, Beike alleges that we failed to use commercially reasonable efforts to deliver to Beike materials and data related to ANKTIVA. Beike is seeking specific performance and declaratory relief for the alleged breaches. On September 25, 2020, the parties entered into a standstill and tolling agreement (standstill agreement) under which, among other things, the parties affirmed they will perform certain of their obligations under the license agreement by specified dates and agreed that all deadlines in the arbitration are indefinitely extended. The standstill agreement could be terminated by any party on ten calendar days' notice, and upon termination, the parties had the right to pursue claims arising from the license agreement in any appropriate tribunal. On March 20, 2023, we terminated the standstill agreement, and on April 11, 2023, Beike served an amended Request for Arbitration. We served an Answer and Counterclaims on May 19, 2023. Beike served a Reply to our counterclaims on June 21, 2023. Beike served its Statement of Claim on March 22, 2024, and the company served its Statement of Defense and Counterclaim on June 21, 2024, and Beike served its Statement of Defense to the Counterclaim and Reply on August 2, 2024. The hearing in the arbitration is scheduled to begin on June 9, 2025. Given that discovery is in the early stages, it remains too early to evaluate the likely outcome of the case or to estimate any range of potential loss. We believe the claims asserted against the company lack merit and intend to defend the case, and to pursue our counterclaims, vigorously.

Securities Class Action

On June 30, 2023, a putative securities class action complaint, captioned *Salzman v. ImmunityBio, Inc. et al.* , No. 3:23-cv-01216-BEN-WVG, was filed in the U.S. District Court for the Southern District of California against the company and three of its officers and/or directors, asserting violations of Sections 10(b) and 20(a) of the Exchange Act. Stemming from the company's disclosure on May 11, 2023 that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the complaint alleges that the defendants had previously made materially false and misleading statements and/or omitted material adverse facts regarding its third-party clinical manufacturing organizations and the prospects for regulatory approval of the BLA. The complaint did not specify the amount of damages being sought. On September 27, 2023, the court appointed a lead plaintiff, approved their selection of lead counsel, and re-captioned the case *In re. ImmunityBio, Inc. Securities Litigation,* No. 3:23-cv-01216. On November 17, 2023, the lead plaintiff filed an amended complaint, which named the same defendants and asserted the same claims as the previous complaint. On January 8, 2024, the defendants filed a motion to dismiss the amended complaint. On June 20, 2024, the court issued an order granting in part and denying in part the motion to dismiss. On July 16, 2024, the lead plaintiff notified the court that he would proceed with his current pleading, and the defendants answered the complaint on August 29, 2024. The company disputes the claims and intends to defend the case vigorously. The company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in this action. If an unfavorable outcome were to occur, it is possible that the impact could be material to the company's results of operations in the period(s) in which any such outcome becomes probable and estimable.

Altor BioScience, LLC, and NantCell, Inc. Matters Against Dr. Hing Wong and HCW Biologics, Inc.

On December 23, 2022, Altor and NantCell filed an arbitration demand against Dr. Hing Wong, former CEO of Altor and NantCell. The demand asserts claims for breach of Dr. Wong's contracts with the companies, breach of the covenant of good faith and fair dealing, conversion, fraudulent concealment, unjust enrichment, breach of fiduciary duty, and replevin. The same

day, Dr. Wong filed an arbitration demand seeking a declaratory judgment finding that Dr. Wong is not liable to Altor or NantCell for any of their claims. The parties have agreed to consolidate the arbitration filings in one proceeding, and on January 23, 2023, Dr. Wong filed an Answering Statement denying the claims.

Also, on December 23, 2022 Altor and NantCell filed a complaint in the United States District Court for the Southern District of Florida against HCW, Dr. Wong's new company. Altor's and NantCell's complaint asserts claims for misappropriation of trade secrets under both Florida and federal law, inducement of breach of contract, tortious interference with contractual relations, inducement of breach of fiduciary duty, conversion, unjust enrichment, replevin, request for assignment of patents and patent applications, and establishment of a constructive trust. On January 31, 2023, HCW filed motions to compel arbitration of Altor's and NantCell's claims, or in the alternative to stay or dismiss them. Altor and NantCell filed an opposition to the motions on February 14, 2023, and HCW filed reply papers on February 21, 2023. At a hearing on April 18, 2023, the court heard argument and requested supplemental briefing. After the hearing, the parties reached an agreement to consolidate all claims in a single arbitration proceeding. On May 1, 2023, we filed our arbitration demand asserting the same claims against HCW that were asserted in the federal court complaint. On May 15, 2023, HCW filed an Answering Statement denying the claims. The hearing in the consolidated arbitration took place from May 20, 2024 to May 30, 2024.

On July 13, 2024, we entered into a Settlement with HCW and Dr. Hing Wong to resolve the claims asserted in the consolidated arbitration and related matters. Under the terms of the Settlement, in part and for no monetary consideration from ImmunityBio, HCW transferred and assigned to ImmunityBio molecules (along with other related assets, including master cell banks, clinical trial protocols, inventory and FDA documents), controlled by HCW that were generated through the use of a TF Platform related to the human TGF-β receptor and TGF-β traps, including, without limitation, HCW9218, HCW9219, HCW9209 and any derivatives thereof or therefrom, including assignment of all patents, know how and all other intellectual property existing as of the Settlement effective date and thereafter that is necessary or reasonably useful for the exploitation of such TGF-β molecules, with the exception that future reasonably useful intellectual property is the subject of a non-exclusive license to ImmunityBio. For indications outside of oncology, ImmunityBio has agreed to grant an exclusive license back to HCW for the transferred intellectual property for TGF-β products, and a non-exclusive license for neoadjuvant ovarian cancer, subject to certain requirements.

In addition, the Settlement provides to ImmunityBio a worldwide, perpetual, irrevocable, fully paid-up, royalty-free, exclusive license to exploit fusion proteins, molecules and/or antibodies created utilizing the TF Platform directed to the receptors of PDL-1, IL-7, IL-12, IL-18, and IL-21, and one additional target to be selected by ImmunityBio within the next six months at its sole discretion, in the oncology field. Furthermore, the Settlement provides additional license terms including, without limitation, a non-exclusive license to ImmunityBio to exploit HCW9201, another fusion protein, and the anti-tissue factor based antibody HCW9101 and the linked resins to manufacture and purify the fusion proteins described above, as well as a right of first refusal for ImmunityBio with respect to any other fusion protein developed by HCW using the TF Platform going forward.

Pursuant to the Settlement, the parties have agreed to mutual, full and complete releases, and the company has agreed to dismiss the consolidated arbitration claims and related matters following HCW's compliance with the terms of the Settlement.

The foregoing summary of the Settlement does not purport to be complete and is qualified in its entirety by reference to the full text of the Settlement, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q.

Shareholder Derivative Action

On October 29, 2024, a shareholder derivative action was filed in the U.S. District Court for the Southern District of California against the members of our Board of Directors and certain officers, captioned *Van Luven v. Soon-Shiong et al.* , Case No. 3:24-cv-02014-L-AHG. Plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant to the action. Stemming from the company's May 11, 2023 disclosure that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the derivative complaint alleges that the individual defendants authorized or permitted materially false and misleading statements and/or omitted material adverse facts regarding ImmunityBio's third-party CMOs and the prospects for regulatory approval of the ANKTIVA BLA. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages on behalf of the company, disgorgement or restitution, declaratory relief, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, any of which may be relevant to decisions regarding an investment in or ownership of our stock. The occurrence of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth, and ability to accomplish our strategic objectives. We have organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below.

Risk Factor Summary

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

- We are a vertically integrated biotechnology company with a single approved product and a limited operating history, and have many other product candidates at the clinical stage. We have a history of operating losses and we expect to continue to incur losses and may never be profitable, which, together with our limited operating history, makes it difficult to assess our future viability.
- We anticipate needing additional financing to fund our operations and complete the commercialization of our approved product and the development and commercialization of our other product candidates.
- The RIPA imposes Revenue Interest Payment obligations, which may adversely affect our financial position and results of operations, as well as affirmative and negative covenants, which restrict our business operations.
- Our debt and revenue interest liability could adversely affect our cash flows and limit our flexibility to raise additional capital.
- The value of our warrants outstanding and the revenue interest liability are subject to potentially material increases and decreases based on fluctuations in the price of our common stock or projected sales and the probability of specific events, which may affect our results of operations and financial position and could adversely affect our stock price.

Risks Related to the Discovery, Development and Commercialization of our Approved Product and our Other Product Candidates

- We are substantially dependent on the successful commercialization of our approved product and the success and regulatory approval of our other product candidates. If we are unable to successfully commercialize our approved product or successfully complete clinical development of, obtain regulatory approval for, or commercialize, our other product candidates, or if we experience delays in doing so, our business will be materially harmed.
- We have limited experience as a commercial company and the sales, marketing, and distribution of our approved product or any future approved products may be unsuccessful or less successful than anticipated.
- We have developed an approved product and are developing other product candidates in combination with other therapies, which exposes us to additional risks.

Risks Related to Reliance on Third Parties

- We have relied and will continue to rely on third parties and related parties to conduct some of our preclinical studies and clinical trials, manufacture products, and perform many essential services for any products that we commercialize, and any failure by a third party, related party, or by us to perform as expected, to comply with legal and regulatory requirements or to conduct the clinical trials according to GCP guidelines, and in a timely manner, may delay or prevent our ability to commercialize our approved product, to seek or obtain regulatory approval for or commercialize our other product candidates or may subject us to regulatory sanctions.
- If third-party manufacturers, wholesalers and distributors fail to perform as expected, or fail to devote sufficient time and resources to our approved product or other product candidates, our clinical development may be delayed, our costs may be higher than expected or our other product candidates may fail to be approved, or we may fail to successfully commercialize our approved product or any other product candidates if approved.

- We use the Clinic, a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or contract with other clinical trial sites, which could delay and/or increase the cost of our development plans.
- We have formed, and may in the future form or seek, strategic alliances or enter into collaborations with third parties or additional licensing arrangements, and we may not realize the benefits of such alliances or licensing arrangements, and we may engage in disputes with such third parties, which can be costly and time consuming.

Risks Related to Healthcare and Other Government Regulations

- We may be unable to obtain U.S. or foreign regulatory approval and, as a result, may be unable to commercialize our other product candidates. We are, and will continue to be subject to ongoing extensive regulation, regulatory obligations and continued regulatory review, which may result in significant additional expense.
- Obtaining and maintaining regulatory approval of our approved product or other product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.
- Even though we have a regulatory approved product, we will continue to be subject to ongoing regulatory requirements concerning it and our other product candidates which may result in significant additional expenses. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our approved product or product candidates.
- If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be successful commercializing our approved product or other product candidates if and when they are approved.
- Problems related to large-scale commercial manufacturing could cause delays in product launches, an increase in product costs, product recalls or product shortages.

Risks Related to Intellectual Property

- If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our approved product and our other product candidates and technologies, we may not be able to compete effectively or operate profitably and our ability to prevent our competitors from commercializing similar or identical technology and we would be adversely affected.
- If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.
- We or our licensors, collaborators, or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other intellectual property or the patents or other intellectual property of our licensors, all of which could be expensive, time-consuming and unsuccessful, may delay or prevent the development and commercialization of our approved product and other product candidates, or may put our patents and other proprietary rights at risk.

Risks Related to Our Common Stock and CVRs

- Dr. Soon-Shiong, our Founder, Executive Chairman, Global Chief Scientific and Medical Officer and principal stockholder, has significant interests in other companies which may conflict with our interests.
- Dr. Soon-Shiong, through his voting control of the company, has the ability to control actions that require stockholder approval.
- Conversion of certain related-party promissory notes, exercise of outstanding warrants and options to purchase our common stock, the achievement of the milestone under our outstanding CVRs, and potential additional equity issuances may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock.
- The market price of our common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.

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

We are a vertically integrated biotechnology company with a single approved product and a limited operating history, and have many other product candidates at the clinical stage. We have a history of operating losses and we expect to continue to incur losses and may never be profitable, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a vertically integrated biotechnology company with a limited operating history upon which you can evaluate our business and prospects regarding the commercialization of our approved product and we have a broad portfolio of product candidates at various stages of development. Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

On April 22, 2024, the FDA approved ANKTIVA for commercial sale, and we have commenced generating revenue, although we expect it to take some time to generate significant revenue from our approved product. We can provide no assurance when, or if, this will occur. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of such other product candidates, and we do not know when, or if, this will occur. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry, including in connection with obtaining marketing approvals, manufacturing a commercial-scale product or arranging for a third party to do so on our behalf, and conducting sales and marketing activities necessary for successful product commercialization. Because of the numerous risks and uncertainties associated with the commercialization of our approved product and other development efforts, we are unable to predict when we may become profitable, if at all.

Since the commencement of our operations, we have incurred significant losses each year, and, as of September 30, 2024, we had an accumulated deficit of $3.3 billion. We expect to continue to incur significant expenses as we seek to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals, increasing our manufacturing capabilities and, upon successful receipt of FDA approval, commercializing our other product candidates. Furthermore, the timing and magnitude of sales of our approved product and other revenues remain uncertain and may take a significant amount of time to materialize.

If we are required by the FDA or any equivalent foreign regulatory authority to perform clinical trials or studies in addition to those we currently expect to conduct, or if there are any delays in completing the clinical trials of our other product candidates, our expenses could increase substantially. In May 2022, we submitted a BLA for our then product candidate, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. In May 2023, we received a CRL from the FDA, indicating that the FDA had determined it could not approve the original BLA submission in its initial form, citing deficiencies related to the FDA's pre-license inspection of our third-party CMOs, among other items and recommendations to address the issues raised.

The CRL that we received in response to our initial BLA submission required us to resubmit the BLA to the FDA addressing the issues in the CRL. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029. We began commercial distribution of our approved product in May 2024, however we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or other product candidates for which we may obtain regulatory approval.

We expect our expenses and net losses to increase significantly as we begin to commercialize our approved product, continue to develop and seek regulatory approvals for, our other product candidates, and plan to commercialize other approved products, if any, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with operating as a public company. Since ANKTIVA is approved for use with BCG, any shortage or supply chain issues associated with BCG could impact the demand for ANKTIVA and our ability to commercialize our approved product.

Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on sales, the timing of our clinical studies and trials, associated manufacturing needs, commercialization activities of our approved product, and any of our other product candidates, if they are approved, and our expenditures on other research and development activities.

We also face the risks associated with the shift from development to commercialization of new products based on innovative technologies. Our ability to achieve profitability, if ever, is dependent upon, among other things, obtaining regulatory approvals for additional product candidates and successfully commercializing our approved product, and other product candidates alone or with third parties. However, our operations may not become profitable even with commercial sales of our approved product or other product candidates, even if they are successfully developed, approved and thereafter commercialized. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. As a result, it may be more difficult for you to assess our future viability than it could be if we had a longer operating history.

We anticipate needing additional financing to fund our operations and complete the commercialization of our approved product and the development and commercialization of our other product candidates, and if we are unable to obtain such financing when needed, or on acceptable terms, we may be unable to complete the successful commercialization of our approved product and the development and commercialization of our other product candidates.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. A significant portion of our funding had been in the form of promissory notes totaling $735.0 million in indebtedness (consisting of related-party promissory notes and accrued and unpaid interest) outstanding as of September 30, 2024 held by entities affiliated with Dr. Soon-Shiong.

As of September 30, 2024, we held cash and cash equivalents, and marketable securities totaling $130.4 million. We will need to obtain additional financing to fund our future operations, including the commercialization of our approved product and the development and commercialization of our other product candidates. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate and we may need to raise additional funds sooner than we presently anticipate. Moreover, research and development and our operating costs and fixed expenses such as rent and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

Unless and until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances or marketing and/or distribution arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all.

To the extent that we raise additional capital through the sale of equity or equity-linked securities (including warrants), convertible debt or under the ATM, our shelf registration statements, or other offerings, or if any of our current debt is converted into equity or if our existing warrants are exercised, your ownership interest will be diluted, and the liquidation or other preferences may adversely affect your rights as a stockholder. If we incur additional indebtedness, our fixed payment obligations will increase, and we may have to comply with certain restrictive covenants that are similar to those associated with the revenue interest liability, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us, or exercise our Call Option (as defined in the RIPA) to purchase the outstanding revenue interest liability, which will require us to generate a significant amount of cash flow to offset these outflows. We have no committed source of additional capital, and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. See "—Our payment obligations under the RIPA may adversely affect our financial position and results of operations and our ability to raise additional capital which in turn may increase our vulnerability to adverse regulatory developments or economic or business downturns" and Note 10, *Revenue Interest Purchase Agreement,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Part I, Item 1. "Financial Information" of this Quarterly Report for more information. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our payment obligations under the RIPA may adversely affect our financial position and results of operations and our ability to raise additional capital, which in turn may increase our vulnerability to adverse regulatory developments or economic or business downturns.

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain Revenue Interests from us for a gross purchase price of $200.0 million paid on closing, less certain transaction expenses. In addition, on May 13, 2024, Oberland purchased additional Revenue Interests from us in exchange for a $100.0 million Second Payment, which we requested upon satisfaction of certain conditions specified in the RIPA, including the receipt of approval by the FDA of our BLA for ANKTIVA on or before June 30, 2024. In consideration for the aforementioned payments, Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, our worldwide net sales, excluding those in China, which are tiered payments ranging from 4.50% to 10.00%, subject to increase or decrease, following December 31, 2029 depending on whether the aggregate payments made to Oberland as of that date met or exceeded the Cumulative Purchaser Payments (as defined in the RIPA). In addition, if the aggregate payments to Oberland as of December 31, 2029 do not equal or exceed the amount of the Cumulative Purchaser Payments, then we are obligated to make a one-time payment to Oberland in an amount equal to 100% of the Cumulative Purchaser Payments, less the aggregate amount of our previous payments to Oberland as of December 31, 2029 (the True-Up Payment, as defined in the RIPA). See Note 10, *Revenue Interest Purchase Agreement*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Part I, Item 1. "Financial Information" of this Quarterly Report for more information.

The RIPA and our payment obligations to Oberland could have important negative consequences to holders of our securities. For example, a portion of our cash flow from operations will be needed to make required payments to Oberland and will not be available to fund future operations.

Payment requirements under the RIPA will increase our cash outflows. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. There is no assurance that if we are required to secure funding we can do so on terms acceptable to us, or at all. Failure to pay amounts owed to Oberland when due would result in a default under the RIPA and could result in foreclosure on all or substantially all of our assets, which would have a material adverse effect.

The RIPA contains affirmative and negative operational covenants and events of default, which may prevent us from capitalizing on business opportunities and taking some corporate actions and give rise to a Put Option in favor of Oberland, which could have a material adverse effect on our financial condition and business operations.

The RIPA contains affirmative and negative covenants and events of default, including covenants and restrictions that, among other things, restrict our ability to incur liens, incur additional indebtedness, make loans and investments, enter into transactions with affiliates, engage in mergers and acquisitions, engage in asset sales and exclusive licensing arrangements, and declare dividends to our stockholders, in each case, subject to certain exceptions set forth in the RIPA. Additionally, Oberland has a Put Option enabling them to terminate the RIPA and to require the company to repurchase the Revenue Interests upon enumerated events such as a bankruptcy event, failure to make a payment, an uncured material breach, default on certain third-party agreements, a breach or default under any subordination agreements with respect to indebtedness to existing stockholders, any right to repurchase or accelerate debt instruments like permitted convertible notes, existing stockholder indebtedness, or subordinated notes during certain time periods, judgments in excess of certain amounts against us, a material adverse effect, the loss of regulatory approval of our approved product, or a change of control. The triggering of the Put Option, including by our failure to comply with these covenants, would permit Oberland to declare certain amounts to be immediately due and payable. If we were to default under the terms of the RIPA, including by failure to make such accelerated payments, Oberland could exercise remedies, including initiating foreclosure proceedings against all or substantially all of our assets. Oberland's right to repayment is senior to the rights of the holders of our common stock. Any triggering of the Put Option or other declaration by Oberland of an event of default under the RIPA could significantly harm our financial condition, business and prospects and could cause the price of our common stock to decline.

Our debt and revenue interest liability could adversely affect our cash flows and limit our flexibility to raise additional capital.

We have a significant amount of debt and revenue interest liability and may need to incur additional debt to support our growth. As of September 30, 2024, our indebtedness totaled $735.0 million, (consisting of related-party promissory notes and accrued and unpaid interest), held by entities affiliated with Dr. Soon-Shiong along with a $300.0 million revenue interest liability with Oberland. Our substantial amount of debt could have important consequences and could:

- require us to dedicate a substantial portion of our cash and cash equivalents to make interest and principal payments on our debt and revenue interest liability payments, reducing the availability of our cash and cash equivalents and cash flow from operations to fund future capital expenditures, working capital, execution of our strategy and other general corporate requirements;
- increase our cost of borrowing and even limit our ability to access additional debt to fund future growth;
- increase our vulnerability to general adverse economic and industry conditions and adverse changes in governmental regulations;
- limit our flexibility in planning for, or reacting to, changes in our business and industry, which may place us at a disadvantage compared with our competitors; and
- limit our ability to borrow additional funds, even when necessary to maintain adequate liquidity, which would also limit our ability to further expand our business.

The occurrence of any of the foregoing factors could have a material adverse effect on our business, results of operations and financial condition.

Further, the company's ability to make scheduled payments of the principal of, potential Test Date payments of, to pay interest or royalties on, or to refinance any current or future indebtedness, including the related-party promissory notes or the revenue interest liability, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient cash flows from operations in the future to service our indebtedness, pay the revenue interest liability, and make necessary capital expenditures. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as selling assets, restructuring indebtedness, including the revenue interest liability, or obtaining additional equity or equity-linked capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness, including the revenue interest liability, at maturity or otherwise, will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

There can be no assurance that we can refinance the related-party promissory notes or revenue interest liability or what terms will be available in the market at the time of refinancing. Furthermore, if prevailing interest rates or other factors at the time of refinancing result in higher interest rates upon refinancing, then the interest expense relating to the refinancing would increase. These risks could materially adversely affect our financial condition, cash flows and results of operations.

The value of our warrants outstanding and the revenue interest liability are subject to potentially material increases and decreases based on fluctuations in the price of our common stock or projected sales and the probability of specific events, which may affect our results of operations and financial position and could adversely affect our stock price.

In connection with our RDOs during the years ended December 31, 2023 and 2022, we entered into warrant agreements with certain institutional investors that allows such investors to purchase up to an aggregate total of 37,732,820 shares of our common stock at exercise prices ranging from $3.2946 per share to $6.60 per share. As of September 30, 2024, 15,490,080 warrants were exercisable and had expiration dates ranging from December 12, 2024 to July 24, 2026.

We account for the warrants as derivative instruments, and changes in the fair value of the warrants are included in *other income (expense), net*, on the condensed consolidated statements of operations for each reporting period. As of September 30, 2024, the fair value of warrant liabilities included in the condensed consolidated balance sheet was $18.3 million. We use the Black-Scholes option pricing model to determine the fair value of the warrants. As a result, the valuation of these derivative instruments is subjective, and the Black-Scholes option pricing model requires the input of subjective assumptions, including the expected stock price volatility and probability of a fundamental transaction (a strategic merger or sale). Changes in these assumptions can materially affect the fair value estimate. We could, at any point in time, ultimately incur amounts different than the carrying value, which could have a significant impact on our results of operations and financial position.

We account for the revenue interest liability as a liability, net of a debt discount comprised of deferred issuance costs, the fair value of a freestanding option agreement related to the SPOA, and the fair value of embedded derivatives requiring bifurcation on the consolidated balance sheet. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. Interest expense is recognized over the estimated term on the consolidated statement of operations. The interest rate on the liability and the underlying value of the bifurcated embedded derivative may vary during the term of the agreement depending on a number of factors, including the level of actual and forecasted net sales, and in the case of the derivative, specific probabilities associated with RIPA Put/Call events or Test Date payments underlying our Monte Carlo analysis. The company evaluates the interest rate quarterly based on actual and forecasted net sales utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales will materially impact the revenue interest liability and/or the bifurcated embedded derivative, interest expense, and the time period for repayment.

Fluctuations in warrant, revenue interest liability, and derivative values, and changes in the assumptions and factors used in the model may impact our operating results, making it difficult to forecast our operating results and making period-to-period comparisons less predictive of future performance. In one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline. In addition, the market price of our common stock may fluctuate or decline regardless of our operating performance.

The accounting method for convertible debt securities could have a material effect on our reported financial results.

In accordance with ASC 470-50, we recorded amendments to our related-party promissory notes entered into on September 11, 2023 under the debt modification accounting model, as the amendments were not substantially different than the terms of the promissory notes prior to the amendment. Under this model, the unamortized debt discounts from the promissory notes are amortized as an adjustment of interest expense over the remaining term of modified promissory notes using the effective interest rate method. Also, the increase in fair value of the embedded conversion feature from the debt modification was accounted for as a debt discount to the $200.0 million convertible note that is not recorded at fair value with a corresponding increase in additional paid-in capital. In addition, we recorded amendments to our related-party promissory notes entered into on December 29, 2023 under the debt extinguishment model, and as a result recognized a total net gain on extinguishment of $36.1 million, which was recorded in *additional paid-in capital,* on the consolidated statement of stockholders' deficit, as the debt was acquired from entities under common control. As a result of the debt amendments, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discount associated with certain promissory notes. We will either report lower net income or a higher net loss in our consolidated financial results because FASB ASC Topic 470-20, *Debt with Conversion and Other Options*, requires interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results and the trading price of our common stock.

We invest our cash on hand in various financial instruments which are subject to risks that could adversely affect our business, results of operations, liquidity and financial condition.

We have typically invested our cash in a variety of financial instruments, including investment-grade short- to intermediate-term corporate debt securities, government-sponsored securities and European bonds; however, after our entry into the RIPA, we can no longer invest our excess funds in corporate or European bonds. Certain of our investments are subject to credit, liquidity, market, and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash and cash equivalents, and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. To manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities to preserve liquidity.

Our ability to use NOLs and research and development credits to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We have not conducted a complete study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If we have experienced a change of control, as defined by Section 382, at any time since inception (including as a result of the March 2021 merger which pursuant to which NantKwest and NantCell combined their businesses), utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before utilization. In addition, our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

Since we will need to raise substantial additional funding to finance our operations, we may experience further ownership changes in the future, some of which may be outside of our control. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. In addition, under the legislation commonly referred to as the TCJA, as modified by the Coronavirus Aid, Relief, and Economic Security Act, the amount of NOLs generated in taxable periods beginning after December 31, 2017, that we are permitted to deduct in any taxable year 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 allows post-2017 unused NOLs to be carried forward indefinitely. Similar rules may apply under state tax laws.

Our transfer pricing policies may be subject to challenge by the IRS or other taxing authorities.

Our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with our determinations as to the value of assets sold or acquired or income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. We believe that our consolidated financial statements reflect adequate reserves to cover such a contingency, but there can be no assurances in that regard.

Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could expose us to greater than anticipated tax liabilities.

The tax laws applicable to our business, including the laws of the U.S. and other jurisdictions, are subject to interpretation and certain jurisdictions may aggressively interpret their laws in an effort to raise additional tax revenue. It is possible that tax authorities may disagree with certain positions we have taken, are currently taking or will take, and any adverse outcome of such a review or audit could have a negative effect on our financial position and results of operations. Further, the determination of our provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded on the consolidated financial statements and may materially affect our financial results in the period or periods for which such determination is made.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. For example, in August 2022, the U.S. enacted the IRA, which imposes a 15% minimum tax on the adjusted financial statement income of certain large corporations, as well as a 1% percent excise tax on corporate stock repurchases by publicly traded companies. Additionally, for taxable years beginning on or after January 1, 2022, the Code eliminated the right to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize U.S. and foreign research and development expenditures over 5 and 15 tax years, respectively. These updates, as well as any other changes to tax laws that are enacted, could adversely affect our tax liability.

Risks Related to the Discovery, Development and Commercialization of our Approved Product and our Other Product Candidates

We are substantially dependent on the successful commercialization of our approved product and the success and regulatory approval of our other product candidates. If we are unable to successfully commercialize our approved product or successfully complete clinical development of, obtain regulatory approval for, or commercialize, our other product candidates, or if we experience delays in doing so, our business will be materially harmed.

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. In addition, now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurances when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, both in terms of amounts and pace, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to FDA by the end of 2029. Our business currently depends heavily on our ability to successfully commercialize our approved product in the U.S. and in other jurisdictions where we may obtain marketing approval. We may never be able to successfully commercialize our approved product or meet our, or analysts or other third parties' expectations with respect to revenues. We have never marketed, sold, or distributed for commercial use any pharmaceutical product other than our approved product, with respect to which we only recently began efforts to initiate commercial sales. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we have built for the launch and commercialization of our approved product in the U.S. or elsewhere will be sufficient for us to achieve success at the levels we expect.

We may encounter issues and challenges in commercializing our approved product and generating substantial revenues. We may also encounter challenges related to reimbursement of our approved product, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering our approved product. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable and as a result physicians may be reluctant to recommend our approved product to their patients. We may face other limitations or issues related to the price of our approved product. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Other factors that may hinder our ability to successfully commercialize approved product, or any of our other product candidates if or when approved and generate substantial revenues, include:

- the acceptance of our approved product by patients and the medical community, including industry groups and third-party payors;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of our approved product at acceptable costs, to remain in good standing with regulatory agencies, and to maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- FDA-mandated package-insert requirements and successful completion of FDA post-marketing requirements;
- the actual market size for our approved product, which may be different than expected;

- the length of time that patients who are prescribed our drug remain on treatment;
- our ability to obtain marketing approval for our approved product outside of the U.S.;
- the sufficiency of our drug supply to meet commercial and clinical demands, which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;
- the availability of reimbursement for our approved product and physicians' understanding regarding the same;
- our ability to effectively compete with other therapies that may emerge for the treatment of bladder cancer; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to our approved product or any of our other product candidates.

Any of these issues could impair our ability to successfully commercialize our approved product or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to our approved product. We may also experience significant fluctuations in sales of our approved product from period to period and, ultimately, we may never generate sufficient revenues from our approved product to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize our approved product in the U.S., and any other international markets where it may subsequently be approved, or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

We have invested a significant portion of our efforts and financial resources in the development of ANKTIVA, our novel antibody-cytokine fusion protein, and our other product candidates, second-generation hAd5 and saRNA vaccine candidates, and our NK cell therapy candidates. Our other product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, enhancement of our commercial organization and service providers, significant marketing efforts, and further investment before we can generate any revenues from the sale of these other potential products. We expect to invest heavily in our other current product candidates and in any future product candidates that we may develop. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials. Furthermore, we cannot assure you that we will meet our timelines for current or future clinical trials, including post-market study requirements for our approved product, which may be delayed or not completed for a number of reasons. Additionally, our ability to generate revenues from our approved product and any other combination therapy products will depend on the availability of the other therapies used in combination therewith, including BCG, with which our approved product and other product candidates are intended to be used. In particular, there has been a shortage of BCG in the U.S. According to the American Urological Association, Merck & Co., Inc. is the sole manufacturer and supplier of BCG in the U.S. and many other countries around the world. Increasing demand for BCG has led to supply constraints for BCG, which can materially impact the demand for our approved product and our ability to commercialize our approved product.

We have limited experience as a commercial company and the sales, marketing, and distribution of our approved product or any future approved products may be unsuccessful or less successful than anticipated.

We recently began commercializing our approved product in the U.S. As a company, we had no prior experience commercializing a product. The success of our commercialization efforts for our approved product and any future approved products is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal and external sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities.

For example, we have hired and contracted for service providers in areas to support commercialization, including in sales management, sales representatives, marketing, access and reimbursement, sales support, and distribution. There are significant expenses and risks involved with establishing our sales, marketing, and distribution capabilities, including our ability to hire, contract for, retain, and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could delay or negatively affect the success of our commercialization efforts and our business. For example, the commercialization of our approved product may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses.

Further, given our lack of experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of our approved product does not develop as quickly as planned, or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

We have developed an approved product and are developing other product candidates in combination with other therapies, which exposes us to additional risks.

We have developed an approved product and are developing other product candidates in combination with one or more other therapies. We are studying ANKTIVA therapy along with other products and product candidates, such as BCG, PD-L1 t-haNK, and hAd5 TAAs. Since we have developed a product, or if we choose to develop other products for use in combination with an approved therapy, we are subject to the risk that the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with the therapy used in combination with our approved product or our other product candidates. In particular, supply chain issues or shortages of other products used in combination with our approved product or any other product candidates could impact our ability to obtain FDA regulatory approval, meet clinical trial timelines, and commercialize our approved product or other product candidates. The FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement or increase our cost of development. It is possible that the results of these trials could show that any positive results are attributable to the already approved product. Following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. If the therapies we use in combination with our approved product or our other product candidates are replaced as the standard of care for the indications we choose for our approved product or any of our other product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delays in clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, quality, manufacturing or supply issues arise with, the therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain approval of or market such other combination therapies.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization of other product candidates.

Our research and development programs of our other non-FDA-approved product candidates are at various stages of development. The clinical trials of our product candidates as well as the manufacturing and marketing of our product candidates will be subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our other product candidates, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our product candidates are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates or their contribution of effect, may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. The clinical trials for our product candidates under development may not be completed on schedule, and regulatory authorities may ultimately disagree with our chosen endpoints or may find that our studies or study results do not support product approval. The FDA or foreign regulatory authorities may not interpret the results as we do or accept the therapeutic effects as valid endpoints in clinical trials necessary for market approval, or they may find that our clinical trial design or conduct does not meet the applicable approval requirement, and more trials could be required before we submit our product candidates for approval. Success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety, tolerability, and efficacy traits despite having progressed through preclinical studies and initial clinical trials and after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising.

In addition, we do not have data on possible harmful long-term effects of our product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our product candidates is uncertain and is subject to significant risk.

The ongoing shortage of BCG may adversely impact market uptake of our approved product, ANKTIVA, and it may also delay our ability to execute our clinical trials or seek new approvals.

There is an ongoing shortage of BCG, which may adversely impact market uptake of our approved product. The BCG shortage may impact the number of patients who are treated with BCG for NMIBC with CIS with or without papillary tumors, therefore limiting the pool of BCG-unresponsive patients who may be candidates for our approved product. In addition, the BCG shortage may also constrain the number of patients we can treat with our approved product since our product is administered along with BCG. In addition, ANKTIVA was awarded *Fast Track* designation by the FDA for the treatment of BCG-naïve NMIBC with CIS. We are currently enrolling patients in our Phase IIb blinded, randomized, two-cohort, open-label, multi-center trial of intravesical BCG with ANKTIVA versus BCG alone, in BCG-naïve patients with high-grade NMIBC with CIS (Cohort A) and NMIBC papillary (Cohort B), which is impacted by the availability of BGC. If we do not complete new trials timely, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our other product candidates in new indications could harm our business, operating results, prospects or financial condition.

We may choose to expend our limited resources on programs that do not yield successful product candidates as opposed to indications that may be more profitable or for which there is a greater likelihood of success.

We do not have sufficient resources to pursue development of all or even a substantial portion of the potential opportunities that we believe will be afforded to us by our product candidates. Because we have limited resources and access to capital to fund our operations, our management must make strategic decisions as to which product candidates and indications to pursue and how much of our resources to allocate to each. Our management must also evaluate the benefits of developing in-licensed or jointly owned technologies, which in some circumstances we may be contractually obligated to pursue, relative to developing other product candidates, indications or programs. Our management has broad discretion to suspend, scale down, or discontinue any or all of these development efforts, or to initiate new programs to treat other diseases. If we select and commit resources to opportunities that we are unable to successfully develop, or we forego more promising opportunities, our business, financial condition, and results of operations will be adversely affected.

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

Since our approved product, current product candidates, and any future product candidates represent novel approaches to treating various conditions, it may be difficult to accurately estimate the potential revenues from our approved product and these other product candidates. Accordingly, we may spend significant capital trying to successfully commercialize our approved product or obtain approval for our other product candidates that have an uncertain commercial market. Our projections of addressable patient populations that may benefit from treatment with our approved product or other product candidates are based on our beliefs and estimates of the therapeutic benefit and adverse event profile of our approved product and other product candidates. These estimates, which have been derived from a variety of sources, including scientific literature, preclinical and clinical studies, surveys of clinics, patient foundations, or market research by third parties, may prove to be incorrect. Further, new studies or approvals of new therapeutics may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our approved product or other product candidates may be limited or may not be amenable to treatment with our approved product or other product candidates and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. Even if we obtain significant market share for our approved product or other product candidates, because the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

There can be no assurance that we will complete a strategic partnership transaction on acceptable terms in accordance with our anticipated timeline, or at all.

We continue to explore potential global strategic partnership transactions for commercialization of ANKTIVA for certain indications. Factors that may impact our ability, or decision, to enter into such a strategic partnership, include, without limitation, the put/call features of the RIPA that may be triggered by entry into a strategic partnership depending on its scope and terms, and ultimately there can be no assurance that we will complete a transaction on acceptable terms, or at all. If we do not execute a strategic partnership transaction in the near-term, it would eliminate a potential source of near-term funding, and may impact our ability to raise additional funds to meet our business needs. In addition, there are significant risks involved with building and managing a commercial infrastructure on a stand-alone basis, which could materialize in the event we do not execute a strategic partnership transaction, or depending on the geographic scope of any executed transaction.

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

From time to time, we may publicly disclose preliminary, interim, or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease, or as inclusion and exclusion criteria is discussed with regulators. We also may make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our clinical trials may not be initiated or completed when we expect, or at all, they may take longer and cost more to complete than we project, our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products, and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA.

We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that any of our other product candidates will receive regulatory approval. A failure of one or more clinical trials can occur at any stage of the clinical trial process, other events may cause us to stop a clinical trial temporarily or permanently, and our future clinical trials may not be successful.

Because our current product candidates include, and we expect our future product candidates to include, candidates based on advanced therapy technologies, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and clinical trial sites outside of the U.S. may not reimburse for costs typically covered by third-party payors in the U.S. As a result, we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products.

Collaborations with other entities may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties, and the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA approval and will increase our future costs.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, slow down our product development and approval process, or impair our ability to commence product sales and generate revenues. In addition, if we make manufacturing changes to our approved product or other product candidates, we may be required to, or we may elect to, conduct additional trials to bridge our modified approved product or other product candidates to earlier versions. These changes may require FDA approval or notification and may not have their desired effect. The FDA may also not accept data from prior versions of the product to support an application, delaying our clinical trials or programs or necessitating additional clinical trials or preclinical studies. We may find that this change has unintended consequences that necessitates additional development and manufacturing work, additional clinical and preclinical studies, or that results in refusal to file or non-approval of a BLA and/or NDA.

Clinical trial delays could shorten any periods during which our product candidates have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, we have in the past experienced clinical holds imposed upon certain of our or investigator-led clinical trials for various reasons, and we may experience further clinical trial holds in the future. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

Even if more of our product candidates are approved and commercialized, we may not become profitable.

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

- price our other product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites for administration of our other product candidates;
- create market demand for our other product candidates through our own or our partner’s marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient population(s) and claims that are necessary or desirable for successful marketing;

- manufacture our other product candidates through third-party CMOs or in our own manufacturing facilities or facilities owned by entities affiliated with Dr. Soon-Shiong in sufficient quantities and at acceptable quality and manufacturing cost to meet regulatory requirements and commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect, and enforce patent and other intellectual property protection and regulatory exclusivity for our other product candidates;
- successfully commercialize any of our other product candidates that receive regulatory approval;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our other product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement for our product candidates;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;
- effectively compete with other therapies or competitors; and
- following launch, ensure that our approved product will be used as directed and that additional unexpected safety risks will not arise.

On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to FDA by the end of 2029. We can provide no assurance with respect to the profitability or the market share that we might achieve for our approved product. The target patient population for which we obtain approval may be narrower than we expect. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our approved product. Further, supply chain issues or shortages associates with combination products that may be used with our approved product, such as ANKTIVA plus BCG, may limit the demand for our approved product.

In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026 with amounts payable in cash or shares of our common stock or a combination thereof. As of September 30, 2024, Dr. Soon-Shiong and his related party hold approximately $139.8 million of net sales CVRs, and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. We may be required to pay the other prior Altor stockholders up to $164.2 million for their net sales CVRs should they choose to have their CVRs paid in cash instead of common stock. If this were to occur, we may need to seek additional sources of capital and any such financing activities may be restricted by the covenants included in the terms of the RIPA. As such, we may face difficulties raising additional capital and may have to accept unfavorable terms and as a result, we may not be able to achieve profitability or positive cash flow.

In connection with our financing in December 2023, we entered into the RIPA with Infinity and Oberland. Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, our worldwide net sales, excluding those in China, which are tiered payments ranging from 4.50% to 10.00%, subject to increase or decrease, following the Test Date depending on whether our aggregate payments made to Oberland as of the Test Date have met or exceeded the Cumulative Purchaser Payments. In addition, if our aggregate payments made as of the Test Date to Oberland do not equal or exceed the amount of the Cumulative Purchaser Payments as of such date, then we are obligated to make a one-time payment True-Up Payment as described above. In addition to other considerations of the RIPA and the associated impact to our profitability and cash flow, if we were required to make a True-Up Payment, we may need to seek additional sources of capital, and we may not be able to achieve profitability or positive cash flow.

If we encounter delays or difficulties enrolling and/or maintaining patients in our clinical trials, our clinical development activities, and receipt of necessary marketing approvals could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties or delays in patient enrollment and retention in our clinical trials for a variety of reasons.

Because the number of qualified clinical investigators is limited, we may need to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, in the past we have engaged, and we intend to continue to engage, in clinical trial efforts outside of the U.S., which gives rise to additional potential complexity and challenges, and further reliance upon third parties in foreign jurisdictions. Moreover, because our product candidates represent a departure from more commonly used methods for cancer and/or viral disease treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies that have established safety and efficacy profiles, rather than enroll patients in any future clinical trial.

Delays or failures in planned patient enrollment or retention may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates or could render further development impossible.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. Combination immunotherapy that includes our current product candidates may be associated with more frequent adverse events or additional adverse events. Undesirable side effects or unacceptable toxicities caused by our other product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials or order our clinical trials to be placed on clinical hold, and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical trials, or preclinical studies should unacceptable toxicities arise. We may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk/benefit perspective. Even if we were to receive product approval, such approval could be contingent on inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or requirements for costly post marketing testing and surveillance, or other requirements, including a REMS to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates. In addition, these serious adverse effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our other product candidates are not normally encountered in the general patient population and by medical personnel. They may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials and which could jeopardize regulatory approval. Any of these occurrences may materially harm our business, financial condition and prospects.

The manufacture of our approved product and other product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers, encounter such difficulties, our ability to gain approval, or to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacture of our approved product and other product candidates involves complex processes, especially for our biologics, vectors and cell therapy product candidates, which are complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics, vectors, and cell therapies is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. The manufacture of fusion proteins, DNA and RNA constructs, and cell therapy products require significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product or other product candidates and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, local, and foreign regulations. We may also find that the manufacture of our approved product or other product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our other product candidates for our clinical trials or, if approved, commercial supply. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. Our approved product and other product candidates are manufactured using processes developed or modified by us, our affiliates, or by our third-party collaborators that we may not utilize for more advanced clinical trials or commercialization.

Currently we manufacture our approved product and other product candidates in our own manufacturing facilities, facilities owned by entities affiliated with Dr. Soon-Shiong and/or through third-party CMOs. Our clinical trials will need to be conducted with product candidates and materials that were produced under cGMP and/or GTP regulations, which are enforced by regulatory authorities. Our approved product and other product candidates may compete with other products and product candidates for access to manufacturing facilities. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing our approved product and other product candidates for us and willing to do so. If our third-party CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our approved product for commercial supply and other product candidates for clinical trials and, if approved, commercial supply of such future products. Further, our third-party CMOs may breach, terminate, or not renew our agreements with them. If we were to need to find alternative manufacturing facilities or transfer between existing facilities it may take us significant time to find a replacement, if we are able to find a replacement at all and it would significantly impact our ability to develop, obtain regulatory approval for or market our approved product and/or other product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

We and our suppliers and third-party CMOs must maintain compliance with cGMP requirements and other applicable regulatory requirements. Any failure to comply with these regulations may require us to cease sales of our approved product or repeat clinical trials, which would delay the regulatory review process of our other product candidates. We may not be able to demonstrate sufficient comparability between products manufactured in different runs at the same or at different facilities to allow for inclusion of the clinical results from patients treated with products from these different runs, in our product registrations or to assure a cGMP process to qualify our other product candidates.

We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so could result in enforcement actions and adverse publicity.

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

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our other product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets, know-how, and other proprietary information from misappropriation or inadvertent disclosure or from being used in such a way as to expose us to potential litigation;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our approved product or other product candidates; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy or personnel turnover at the manufacturer or supplier.

Moreover, any problems or delays we or our third-party CMOs experience in preparing for commercial scale manufacturing of a product candidate may result in a delay in the FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. Furthermore, if we or our third-party CMOs fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues. We may ultimately be unable to reduce the cost of goods for our other product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

In addition, the manufacturing process and facilities for our approved product and any other products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our third-party CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary CMC documentation in support of a BLA or NDA on a timely basis. Our or our third-party CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our third-party CMOs will be able to successfully pass all aspects of a pre-approval or continued inspection by the FDA or other foreign regulatory authorities On May 9, 2023, the FDA delivered a CRL to us regarding the BLA filed in May 2022, indicating that the FDA had determined that it could not approve the original BLA submission in its initial form, and the FDA made recommendations to address the issues raised. The deficiencies in the CRL related to the FDA's pre-license inspection of the company's third-party CMOs, among other items. On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors.

Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product or other product candidates that may not be detectable in final product testing. If microbial, viral, environmental, or other contaminants are discovered in our product or other product candidates or in the manufacturing facilities in which our product or other product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay commercial sales and clinical trials and adversely harm our business. If we or our third-party CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the initial or continued approvals we need to commercialize such products. There is no assurance that either we or our third-party CMOs will be able to manufacture our approved product or any subsequently approved product candidate to specifications acceptable to the FDA or other regulatory authorities, to produce our product or other product candidates in sufficient quantities to meet the requirements for the launch of such products, or to meet potential future demand.

Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product or other product candidates to perform differently and affect our commercial sales or the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could cause commercial sales to cease, delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, and jeopardize our ability to commercialize our other product candidates, if approved, and generate revenues.

To the extent we use third-party CMOs, we are ultimately responsible for the manufacture of our products, once approved, and our other product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the federal civil FCA, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could cause us to cease commercial sales, delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be successful in managing the build-out of our manufacturing facilities and associated costs or satisfying manufacturing-related regulatory requirements.

We have entered into facility leases for our planned manufacturing operations and related activities under which we are responsible for the build-out of the facility space and associated costs. The build-out of these facilities and related equipment purchases are complex and specialized and will involve substantial capital expenditure, and it could take longer, and cost more, than currently expected. Significant delays and/or cost overruns would result in higher expenditures and could be disruptive to operations, any of which could have a negative impact on our financial condition or results of operations. For example, during the first quarter of 2022 we acquired a leasehold interest in the 409,000 square foot Dunkirk Facility as described below. While we believe that governmental funding will assist in funding a small portion of the further build-out of the Dunkirk Facility, we will need to plan and fund most of the additional build-out of, and purchase additional equipment for, the Dunkirk Facility in connection with our planned full operations. In addition, it is possible that, once built, the leased facilities may prove to be less conducive to our operations than is currently anticipated, resulting in operational inefficiencies or similar difficulties that could prove difficult or impossible to remediate and result in an adverse impact on our financial condition or results of operations.

We also may not successfully realize the anticipated benefits from the capital expenditure at such facilities based on factors such as delays and uncertainties regarding development, regulatory approval, and commercialization of our product candidates, as well as the potential to lose access to the leased facilities.

Further, in the future if we transition from our current third-party CMOs to our own manufacturing facilities, or to alternative third-party CMOs, for one or more of our products or other product candidates, including our approved product, we will need to conduct additional preclinical, analytical and/or clinical testing and obtain FDA approval before such manufacturing changes are implemented. If we are unsuccessful in demonstrating the comparability of supplies before and after a manufacturing change, such manufacturing change can result in a delay or disruption in our clinical development plan or our ability to commercialize any approved product. Any production shortfall that impairs the supply of our product or other product candidates could negatively impact our ability to sell our approved product, complete clinical trials, obtain regulatory approval, and commercialize our other product candidates. A product shortfall could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for our product or other product candidates, which could materially and adversely affect our revenue and results of operations.

In addition, our planned operations, including our development, testing, and future manufacturing activities, are subject to numerous environmental, health, and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that may have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Failure to successfully complete our build-outs and successfully operate our planned manufacturing facilities and satisfy manufacturing-related regulatory requirements could adversely affect the commercial viability of our product candidates and our business.

Cell-based therapies and biologics rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our approved product and any future products, if approved.

We currently depend on a small number of suppliers for some of the materials used in, and processes required to develop, our approved product and other product candidates. For some of these reagents, equipment, and materials used in the manufacture of our approved product and other product candidates, we rely, and we may in the future rely, on sole source vendors or a limited number of vendors. Some of these suppliers may not have the capacity to support commercial scale or clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing. An inability to continue to source product from any of these suppliers could adversely affect our ability to satisfy demand for our approved product and other product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we seek to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform both *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Because our approved product and other product candidates represent, and our other potential product candidates will represent, novel approaches to the treatment of disease, there are many uncertainties regarding the development, market acceptance, public opinion, third-party reimbursement coverage, and the commercial potential of our approved product and other product candidates, which may impact public perception of us and our approved product and other product candidates and which may adversely affect our ability to conduct our business and implement our business plans.

Human immunotherapy products are a new category of therapeutics. We use relatively novel technologies involving ANKTIVA, hAd5, saRNA and yeast constructs, and cell-based therapies, and our NK cell platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals. Because this is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement, and the commercial potential for our approved product and other product candidates. There can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. Adverse public attitudes may adversely impact our ability to enroll patients in clinical trials. The FDA may take longer than usual to come to a decision on any BLA and/or NDA that we submit and may ultimately determine that there is not enough data, information, or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as REMS, until more experience with our other product candidates is obtained. Finally, after increased usage, we may find that our product or other product candidates do not have the intended effect, do not work with other combination therapies or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the commercialization of our approved product and development and commercialization of our product candidates or demand for our product or any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

There is no assurance that the approaches offered by our approved product or other product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for our proposed product candidates. Public perception may be influenced by claims, such as claims that our technologies are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general could result in greater government regulation and stricter labeling requirements of immunotherapy products, including our other product candidates, and could cause a decrease in the demand for our approved product and any other products we may develop. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product or other product candidates target prescribing, and their patients being willing to receive treatments that involve the use of our product or other product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. The market for any products that we successfully develop will also depend on the cost of the product. Our goal is to reduce the cost of manufacturing and providing our therapies. However, unless we can reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our product or potential products, we will not become profitable, which would materially and adversely affect the value of our common stock. Our ANKTIVA therapies and our other therapies may be provided to patients in combination with other agents provided by third parties or our affiliates. The cost of such combination therapy may increase the overall cost of therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our approved product or other product candidates.

We face an inherent risk of product liability as a result of the commercialization of our approved product and clinical development, testing and manufacturing of our other product candidates. For example, we may be sued if our approved product or other product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. Large judgements have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our approved product or other product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in a regulatory investigation of the safety and effectiveness of our products, our third-party manufacturer's manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates may be used or suspension or withdrawal of approvals, decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our approved product or other products we may develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to product liability claims for which we have no coverage. While we have obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We will face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer and infectious disease therapy is intense and is accentuated by the rapid pace of technological development. We compete with a variety of multi-national biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. These competitors have developed, may develop, and are developing product candidates and processes competitive with our approved product or other product candidates. Research and discoveries by others may result in breakthroughs which may render our approved product or other product candidates obsolete even before they generate any revenues. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which our product treats or for which we are developing product candidates. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the U.S. and internationally. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical, and human resources than we do, as well as significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful in obtaining approval of treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive, possibly even before we are able to enter the market. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The availability and price of our competitors' products could limit the demand and the price we are able to charge for our approved product or any of our other product candidates, if approved. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

We may not be able to implement our business plan if the acceptance of our approved product or other product candidates is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our approved product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our products for use in limited circumstances. We may be adversely impacted if any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise.

We may seek orphan drug status or Breakthrough Therapy or Fast Track designations or other designation for one or more of our product candidates, but even if any such designation or status is granted, it may not lead to a faster development process or regulatory review and may not increase the likelihood that our product candidates will receive marketing approval, and we may be unable to maintain any benefits associated with such designations or status, including market exclusivity.

In 2012, the FDA established a *Breakthrough Therapy* designation, which is intended to expedite, although there is no guarantee, the development and review of products that treat serious or life-threatening conditions. We have been awarded, and may seek in the future, *Breakthrough Therapy* or *Fast Track* designation for current or future product candidates. Receipt of a designation to facilitate product candidate development is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidates no longer meet the designation conditions.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available the drug or biologic will be recovered from sales in the U.S. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA to market the same drug or biologic for the same indication for seven years, except in limited circumstances. We may seek orphan drug status for one or more of our product candidates, but exclusive marketing rights in the U.S. may be lost if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In response to *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the FDA clarified in a January 2023 notice that it intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

As a condition of approval, the FDA may require that we implement various post-marketing requirements and conduct post-marketing studies, any of which would require a substantial investment of time, effort, and money, and which may limit our commercial prospects.

As a condition of biologic licensing, the FDA is authorized to require that sponsors of approved BLAs implement various post-market requirements, including REMS and Phase 4 trials. In connection with the regulatory approval of ANKTIVA, we are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029. If we receive approval of our other product candidates, the FDA may determine that similar or additional or more burdensome post-approval requirements are necessary to ensure that our product candidates are safe, pure and potent. For example, in connection with FDA approval of another company's drug, the FDA required significant post-marketing commitments, including a Phase 4 trial, revalidation of a test method, and a substantial REMS program that included, among other requirements, the certification of hospitals and their associated clinics that dispensed the drug, including the implementation of a training program and limited distribution only to certified hospitals and their associated clinics. To the extent that we are required to establish and implement any post-approval requirements, we will likely need to invest a significant amount of time, effort and money. Such post-approval requirements may also limit the commercial prospects of our product candidates.

We have never commercialized a product candidate before our approved product, and we may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators. We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties or related parties to market and sell our other product candidates, if they are approved, and as a result, we may be unable to generate product revenues.

We have little to no prior experience in the marketing, sale and distribution of biopharmaceutical products. To achieve commercial success for our approved product and other product candidates, which we may license to others, we may rely on the assistance and guidance of those collaborators. In order to commercialize our approved product and our other product candidates for which we retain commercialization rights and marketing approval, if approved, we must continue to build out our marketing, sales and distribution capabilities, including a comprehensive healthcare compliance program, and/or arrange with third parties to perform these services, which will continue to take time and require significant financial expenditures, and could delay any product launch and we may not be successful in doing so. There are significant risks involved with building and managing a commercial infrastructure. We, or our collaborators and third-party contractors, have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage and retain medical affairs, marketing, sales and commercial support personnel. Recruiting, training, and retaining a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of our approved product or any other product candidate for which we or our third-party contractors recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In the event we are unable to develop a commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Even if we and/or our third-party contractors are able to effectively establish a sales force and develop a marketing and sales infrastructure, such sales force and marketing teams may not be successful in commercializing our approved product or any other current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, which we are doing to a certain extent in connection with our approved product launch, we may have less control over their sales efforts and could be held liable if they failed to comply with applicable legal or regulatory requirements.

If our approved product or any of our other product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

We are in the process of commercializing our approved product. Our approved product and other product candidates, if approved by the appropriate regulatory authorities for marketing and sale, may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If our approved product or any other product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate significant product revenues or become profitable. Market acceptance of our approved product or any other product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market. Efforts to educate the medical community and third-party payors on the benefits of our approved product and other product candidates may require significant resources and may not be successful. Even if the medical community accepts that our approved product and other product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such approved product or other product candidates and may be slow to adopt them as an accepted treatment of the approved indications, including, for example, if third-party payors require high co-payments or if physicians perceive that reimbursement will not be available on a timely basis or at all. If our product or any of our other product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our approved product or any of our other product candidates will depend on a number of factors, including:

- the continued safety and efficacy of our approved product or other product candidates;
- the prevalence and severity of adverse events associated with such approved product or other product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;

- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products or distribution and use restrictions imposed by the FDA with respect to such approved product or other product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such approved product or other product candidates;
- the relative difficulty of administration of such approved product or other product candidates;
- our ability to offer such product or other product candidates for sale at competitive prices, including the cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such approved product or other product candidates;
- the safety, efficacy and other potential advantages over, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such approved product or other product candidates, as well as competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

If our approved product or any other product candidate that we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Our approved product and our product candidates may face competition sooner than anticipated.

The enactment of the BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, the FDA cannot make an approval of an application for a biosimilar product effective until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest or other related entity do not qualify for the 12-year exclusivity period.

Our approved product and/or product candidates may qualify for the BPCIA's 12-year period of exclusivity. There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our approved product or any other product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not block companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Even if we receive a period of BPCIA exclusivity for our approved product, if subsequent products do not include a modification to the structure of the product that impacts safety, purity, or potency, we may not receive additional periods of exclusivity for those products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference product candidates in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Medicare Part B encourages use of biosimilars by paying the provider the same percentage of the reference product average sale price as a mark-up, regardless of which product is reimbursed. It is also possible that payors will give reimbursement preference to biosimilars even over reference biologics absent a determination of interchangeability.

For our small molecular product candidates, if qualified, the regulatory exclusivity period is less than for our biologic product candidates. The FD&C Act provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a drug where the FDA has not previously approved any other new drug containing the same active molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated NDA or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FD&C Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, which were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. As such, we may face competition from generic versions of our small molecule product candidates, which will negatively impact our long-term business prospects and marketing opportunities.

We will need to obtain FDA approval of any proposed branded product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our product candidates in the U.S. will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe or otherwise violate the existing rights of third parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new product name in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our systems, infrastructure or data, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, may or may be perceived to fail or suffer a cyberattack, security breach or other incident, including a breakdown or compromise of the confidentiality, integrity and availability of our systems, networks or data, which could adversely affect the operation of our business and reputation.

We are and will be dependent upon information technology systems, infrastructure, and data. In the ordinary course of our business, we will directly or indirectly collect, store, transmit, and otherwise process sensitive and confidential information, including intellectual property, preclinical, and clinical trial data, proprietary business information, and personal information of our clinical trial patients and employees, including in our data centers and on our systems and networks or on those of third parties. The secure maintenance, transmission, and processing of data is critical to our operations. The multitude and complexity of our systems and those of our CROs, CMOs, clinical sites, or other contractors or consultants may subject them to various threats, including interruption, destruction, malicious intrusion, and random attack. Privacy or security breaches or other incidents, including by third parties, employees, contractors or others, may pose a risk that sensitive or confidential information, including our intellectual property, trade secrets or personal information of our employees, patients, or other business partners may be exposed to unauthorized persons or to the public. Further, as many of our employees work remotely, our reliance on our and third-party systems has increased substantially and is expected to continue to increase.

Despite the implementation of security measures, our systems, infrastructure and data, and those of our CROs, CMOs, clinical sites and other contractors and consultants, are subject to risks relating to cyberattacks, security breaches, or other incidents, including through viruses and other malware, employee error, unauthorized access, natural disasters, terrorism, war, fire, telecommunication and electrical failures, denial of service attacks, social engineering (including phishing attacks) and other means. As the cyberthreat landscape evolves, these cyberattacks are increasing in their frequency, sophistication and intensity and are becoming increasingly difficult to detect. The techniques used by cybercriminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Cyberattacks affect service reliability and threaten data confidentiality, integrity and availability. While we and our shared services partner, NantWorks, have invested, and continue to invest, in the protection of our data, systems, and infrastructure, there can be no assurance that our efforts, or the efforts of our partners, vendors, CROs, CMOs, clinical sites and other contractors and consultants, will be successful. Any failure or perceived failure in our systems, infrastructure or data, or to identify or prevent cyberattacks, security breaches or other incidents, including service interruptions could adversely affect our business and operations, result in the loss, unavailability, misuse, unauthorized use or acquisition, or other unauthorized processing of critical or sensitive information, and result in financial, legal, business or reputational harm. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to any such failures, security breaches, cyberattacks or other incidents.

If any such event were to occur, it could also cause interruptions in our operations, including a disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data or may limit our ability to effectively execute a product recall, if required. Any such event could result in liability, delays in the development and commercialization of product candidates, claims, demands or proceedings initiated by regulatory authorities or private parties, violations of laws, including laws that protect the privacy or security of personal information, significant liabilities, including regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or the perception of its effects, may materially and adversely affect our business, operations and financial condition.

Public health outbreaks, such as epidemics or pandemics may significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time due to the spread of the disease, due to shutdowns that may be requested or mandated by federal, state, and local governmental authorities or certain employers, or due to the economic consequences associated with the pandemic. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities and the facilities of our partners, clinical trial sites, service providers, suppliers, or contract manufacturers. For example, the COVID-19 pandemic caused a temporary disruption in our ability to recruit participants for our clinical trials in the calendar year 2020 and the first quarter of 2021. While it is not possible to predict whether another pandemic, epidemic, or infectious disease outbreak similar to COVID-19 will materialize, any measures taken by governments and local authorities in response to such future health crises have the potential to disrupt and delay the initiation of new clinical trials, the progress of our ongoing clinical trials and our preclinical activities, and potentially the manufacture or shipment of both drug substance and finished drug product of our approved product and our other product candidates for preclinical testing and clinical trials, may adversely impact our business, financial condition, or operating results.

Risks Related to Reliance on Third Parties

We have relied and will continue to rely on third parties and related parties to conduct some of our preclinical studies and clinical trials, manufacture our approved product and other product candidates, and perform many essential services for any products that we commercialize, including services related to sales and marketing, distribution, government price reporting, customer service, accounts receivable management, cash collection and adverse event reporting. Any failure by a third party, related party, or us to perform as expected, to comply with legal and regulatory requirements or to conduct the clinical trials according to GCP guidelines, and in a timely manner, may delay or prevent our ability to commercialize our approved product, to seek or obtain regulatory approval for or commercialize our other product candidates or may subject us to regulatory sanctions.

We have relied and will continue to rely on third parties and related parties to conduct some of our preclinical studies and clinical trials, manufacture our approved product and other product candidates, and perform many essential services for our approved product and any products that we commercialize. Any failure by a third party, related party, or by us to perform as expected, to comply with legal and regulatory requirements or to conduct the clinical trials according to GCP guidelines, and in a timely manner, may delay or prevent our ability to commercialize our approved product, to seek or obtain regulatory approval for or commercialize our other product candidates, or may subject us to regulatory sanctions.

Large-scale clinical trials require significant financial and management resources. We expect to be heavily reliant on third and related parties, including medical institutions, academic institutions, clinical investigators or CROs to conduct, supervise or monitor some or all aspects of our clinical trials, and in some cases, third-party CMOs to manufacture our approved product or other product candidates, which may force us to encounter delays and challenges that are outside of our control. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. Our CROs and other third parties must communicate and coordinate with one another in order for our trials to be successful. We have a limited history of conducting clinical trials and have limited experience as a company in submitting and supporting the applications necessary to gain marketing approvals. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with GLP guidelines, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us and the third parties upon which we intend to rely for conducting our clinical trials to comply with GCP guidelines for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA or NDA is filed with the FDA) of trial sponsors, clinical investigators, trial sites, and certain third parties including CMOs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP guidelines or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and have to be repeated, and our submission of marketing applications may be delayed or the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP guidelines.

We rely on third parties to manufacture, package, label, and ship our approved product and some of our other product candidates for the clinical trials that we conduct. Any performance failure on the part of these third parties could delay commercialization of our product or other product candidates or the clinical development or marketing approval of our product candidates producing additional losses and depriving us of potential product revenues.

Our CROs, clinical trial sites, and other third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If these third parties conducting our clinical trials (i) do not successfully carry out their contractual duties, (ii) do not meet expected deadlines, (iii) experience work stoppages, (iv) do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, (v) need to be replaced, (vi) experience financial hardships, or (vii) terminate their agreements with us or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCP guidelines, or other regulatory requirements or for other reasons, our trials may need to be repeated, extended, delayed, or terminated, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. Additionally, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties, which we may not be able to do on commercially reasonable terms, or at all and which may involve additional cost and time and require management time and focus. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Furthermore, if any of the third parties conducting our clinical trials experience any financial hardships due to difficulties relating to the operation of their business, it could damage our business, financial condition, results of operations, and prospects. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay the continued development of our product candidates using the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

We have and we expect to continue to retain third-party service providers to perform a variety of functions related to the sale of our approved product and current or future product candidates, key aspects of which will be out of our direct control. These service providers may provide key services related to sales, market access, distribution, customer service, accounts receivable management, state reporting, compliance support, and cash collection. If we retain a service provider, we will substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage in the future with third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates, and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions.

Additionally, we have contracted with one or more third parties to calculate and report pricing information mandated by various government programs, and may enter into further contracts in the future. If a third party fails to timely report or adjust prices as required or errs in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or FCA lawsuits.

Our reliance on third and related parties can also present intellectual property-related risks. For example, collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or technology or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property. Collaborators may also own or co-own intellectual property covering our product candidates or technology that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or technology. Collaborators may also gain access to our trade secrets or formulations and impact our ability to commercialize proprietary technology. We may also need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us.

We also anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by ANKTIVA will involve further investigator-led clinical trials. While these trials generally provide us with valuable clinical data that can inform our future development strategy, we generally have less control over not only the conduct but also the design of these clinical trials. Third-party investigators may design clinical trials involving our product candidates with clinical endpoints that are more difficult to achieve or in other ways that increase the risk of negative clinical trial results compared to clinical trials we may design on our own. Negative results from investigator-led clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our business and the perception of our product candidates.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services.

If third-party manufacturers, wholesalers, and distributors fail to perform as expected, or fail to devote sufficient time and resources to our approved product or other product candidates, our clinical development may be delayed, our costs may be higher than expected or our other product candidates may fail to be approved, or we may fail to commercialize our approved product or any other product candidates, if approved.

Our reliance on third-party manufacturers, wholesalers, and distributors exposes us to the following risks, any of which could delay FDA approval of our product candidates and commercialization of our approved product or any other product candidates, if approved, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver our approved product or other product candidates for regulatory, compliance, and other reasons;
- our CMOs, wholesalers, and distributors could breach or default on their agreements with us to meet our requirements for commercialization of our approved product or other product candidates;
- our CMOs, wholesalers, and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell, and distribute our approved product or other product candidates and we may incur additional cost;
- our CMOs, wholesalers, and distributors may misappropriate our proprietary information; and
- if our CMOs, wholesalers, and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay our commercial programs.

Our reliance on third parties reduces our control over our approved product and other product candidate development activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and industry standards. For example, the FDA and other regulatory authorities require that our approved product, other product candidates and any other products that we may eventually commercialize be manufactured according to cGMP requirements. Any failure by our third-party manufacturers to comply with cGMP or maintain a compliance status acceptable to the FDA or other regulatory authorities or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. On May 9, 2023, the FDA delivered a CRL to us regarding the BLA filed in May 2022, indicating that the FDA had determined that it could not approve the original BLA submission in its initial form, and the FDA made recommendations to address the issues raised. The deficiencies in the CRL related to the FDA's pre-license inspection of the company's third-party CMOs, among other items.

The CRL that we received in response to our initial BLA submission required us to resubmit the BLA to the FDA addressing the issues in the CRL. On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. Our third-party manufacturers are subject to periodic inspections by the FDA and other regulatory authorities, and failure to comply with cGMP could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for our approved product or our other product candidates previously granted to us, or take other regulatory or legal action, including a request to recall or seize our approved product or our other product candidates, total or partial suspension of production, suspension of clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of other product candidates, injunction, imposing civil penalties or pursuing criminal prosecution.

Additionally, as we scale up manufacturing of our approved product or other product candidates and conduct required stability testing, we may encounter additional challenges or cGMP issues. These issues may require refinement or resolution in order to proceed with commercial marketing of our approved product or any of our other product candidates, if approved. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our manufacturing process could result in increased scrutiny by regulatory authorities, delays in our regulatory review process, increases in our operating expenses, or failure to obtain or maintain approval for our approved product or other product candidates. If such issues relate to an approved product, we may not be able to commercialize the approved product as we planned or fail to meet commercial demand, any of which can materially and adversely affect our position in the market.

We use the Clinic, a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or contract with other clinical trial sites, which could delay and/or increase the cost of our development plans.

The Clinic has conducted, is currently conducting, and in the future may conduct, clinical trials involving our product candidates. The Clinic is a related party as it is owned by an officer of the company and additionally, NantWorks manages the administrative operations of the Clinic. Prior to June 30, 2019, one of the company's officers was an investigator or sub-investigator for certain of the company's trials conducted at the Clinic. NantWorks, which is wholly owned by our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, provides certain administrative services (and has loaned money) to the Clinic. Under certain circumstances, we may be required to report some of these relationships to the FDA.

Relying on a related-party clinical site to develop data that is used as the basis to support regulatory approval can expose us to significant regulatory risks. The FDA may conclude that a financial relationship between us, the Clinic and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. If any data integrity, or regulatory non-compliance issues occur during the study, we may not be able to use the data for our regulatory approval. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We have formed, and may in the future form or seek, strategic alliances or enter into collaborations with third parties or additional licensing arrangements, and we may not realize the benefits of such alliances or licensing arrangements. Conflicts may arise between us and our collaborators or strategic partners, and such strategic alliances, collaborations or licensing arrangements may not be successful.

We have formed, and may in the future form or seek, strategic alliances, or enter into collaborations with third parties or additional licensing arrangements that we believe will complement or augment our development and commercialization efforts with respect to our approved product, other product candidates and any future product candidates that we may develop. We plan to collaborate with governmental, academic, and corporate partners, including affiliates, to improve and develop ANKTIVA, hAd5, saRNA and yeast constructs, and other cell therapies for new indications for use in combination with other therapies and to improve and develop other product candidates, which may expose us to additional risks, or we may not realize the benefits of such collaborations.

Because some of our collaborations are conducted at outside laboratories, and we do not have complete control over how the studies are conducted or reported, the results of such studies, which we may use as the basis for our conclusions, projections, or decisions with respect to our current or future product candidates, may be incorrect or unreliable, or may have a negative impact on us if the results of such studies are imputed to our product candidates or proposed indications, even if such imputation is improper. Additionally, we may use third-party data to analyze, reach conclusions or make predictions or decisions with respect to our product candidates that may be incomplete, inaccurate or otherwise unreliable.

We also plan to collaborate with governmental, academic and corporate partners, including affiliates, to improve and develop ANKTIVA, hAd5, saRNA and yeast constructs, cell therapies and other therapies for new indications for use in combination with other therapies and to improve and develop other product candidates, which may expose us to additional risks, or we may not realize the benefits of such collaborations.

Furthermore, conflicts may arise between us and our collaborators or strategic partners, and such strategic alliances, collaborations, or licensing arrangements may result in litigation, which is expensive and time consuming. For example, in 2019, Sorrento, with which we jointly established a new entity called NANTibody as a stand-alone biotechnology company, commenced litigation against us and certain of our officers and directors, alleging that we improperly caused NANTibody to acquire IgDraSol. Additionally, in 2020 we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration, served by Beike asserting breach of contract under our subsidiary Altor's license agreement with them. See Item 1. "*Legal Proceedings*" for more information regarding these disputes. Any such developments could harm our product development efforts, and additional disputes with our licensors or strategic collaborators may be expensive and time consuming.

In addition, collaborations involving our product candidates will be subject to numerous risks, which may include the following:

- collaborators, including their related or affiliated companies, may be entitled to receive exclusive rights for or involving our products;
- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain, defend, or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development, or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- if an agreement with any collaborator terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates using the collaborator's technology or intellectual property or require us to stop development of those product candidates completely; and
- collaborators may own or co-own intellectual property covering our product candidates or technology that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. Additionally, exclusive rights that we may grant in connection with collaboration agreements may limit our ability to enter into new or additional collaboration agreements or strategic partnerships if we experience issues with existing collaborations. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our existing academic collaborators and strategic partners are conducting multiple product development efforts. Such current or future collaborators or strategic partners could become our competitors in the future and could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the commercialization of our approved product and the development and commercialization of our other product candidates. Competing product candidates, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborator's or partner's support for our product or product candidates.

Our use of joint ventures, strategic partnerships, and alliances may expose us to risks associated with jointly owned investments.

We may operate parts of our business through joint ventures, strategic partnerships, and/or alliances with other companies. While such arrangements may, in some cases, give us access to technologies that we may not otherwise have or may give us access to capital, they involve risks not otherwise present in our own investments, including: (i) we may not control the venture, and it may divert management time and resources ; (ii) the partner(s) may not agree to distributions that we believe are appropriate; (iii) we may experience impasses or disputes with such partner(s) on certain decisions, which could require us to expend additional resources to resolve such impasses or disputes, including litigation or arbitration; (iv) our partner(s) may become insolvent or bankrupt, fail to fund their share of required capital contributions or fail to fulfil their obligations as a venture partner; (v) the arrangements governing these relationships may contain certain conditions or milestone events that may never be satisfied or achieved; (vi) our partner(s) may have business or economic interests that are inconsistent with our interests and may take actions contrary to our interests; (vii) we may suffer losses as a result of actions taken by the partner(s); and (viii) it may be difficult for us to exit if an impasse arises or if we desire to sell our interest for any reason. For example, in December 2021 we established a joint venture with Amyris. However, in August 2023, Amyris announced that it had filed for Chapter 11 bankruptcy protection. As of September 30, 2024, the carrying amount of our equity investment in the joint venture was zero. There can be no guarantee that the strategic partnerships that we currently have or may enter into will be successful. Furthermore, we may, in certain circumstances, be liable for the actions of our partners. Any of the foregoing risks could have a material adverse effect on our business, financial condition and results of operations.

We are heavily dependent on our senior management, particularly Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, and a loss of a member of our senior management team in the future, even if only temporary, could harm our business.

Our operations will be dependent upon the services of our executives and our employees who are engaged in research and development. If we lose the services of members of our senior management, particularly Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, for a short or an extended time, for any reason, we may not be able to find appropriate replacements on a timely basis, and our business, financial condition and results of operations could be materially adversely affected. Our existing operations and our future development depend to a significant extent upon the performance and active participation of certain key individuals, particularly Dr. Soon-Shiong. Although Dr. Soon-Shiong focuses heavily on our matters and is highly active in our management, he does devote a significant amount of his time to a number of different endeavors and companies, including NantHealth, Inc., NantMedia Holdings, LLC (which operates the Los Angeles Times) and NantWorks, which is a collection of multiple companies in the healthcare and technology space. The risks related to our dependence upon Dr. Soon-Shiong are particularly acute given his ownership percentage, the commercial and other relationships that we have with entities affiliated with him, his role in our company and his public reputation. We may also be dependent on additional funding from Dr. Soon-Shiong and his affiliates, which may not be available when needed and which he is under no obligation to provide.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided, and plan to continue providing, equity incentive awards that vest over time. The value to employees of equity incentive awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We do not have employment agreements with our NEOs and do not maintain “key man” insurance policies on the lives of most of the members of our management.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

Our future financial performance and our ability to commercialize our approved product and other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of their attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. In order to develop our business in accordance with our business plan, we will have to hire additional qualified personnel, including in the areas of research, manufacturing, clinical trials management, regulatory affairs, and sales and marketing. We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term. However, competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need, on acceptable terms or at all. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely, and for the foreseeable future we expect to rely, in substantial part, on certain independent organizations, advisors, and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements on economically reasonable terms, or at all. In addition, if we are unable to effectively manage our outsourced activities or if the quality, compliance, or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further commercialize our approved product or develop and commercialize our other product candidates and, accordingly, may not achieve our research, development, and commercialization goals on a timely basis, or at all.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- assimilation of operations, intellectual property, and products of an acquired company or product, including difficulties associated with integrating new personnel;
- the diversion of our managements' attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- significant upfront milestone and/or royalty payments from which we may not realize the anticipated benefits;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens (including increased cash requirements). In addition, if we undertake acquisitions, we may issue dilutive equity securities, assume or incur additional debt obligations or contingent liabilities, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

A variety of risks associated with marketing our approved product and other product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our approved product and other product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the coronavirus pandemic; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

In particular, there is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

We are party to a public-private partnership regarding our manufacturing facility in Dunkirk, New York, and if we or our counterparties fail to meet the obligations of those agreements, it could materially impact our development, operations and prospects.

On February 14, 2022, we acquired a leasehold interest in the Dunkirk Facility from Athenex, which we believe will provide us with a state-of-the-art biotech production center that will substantially expand and diversify our manufacturing capacity in the U.S. and the ability to scale production associated with certain of our product candidates.

We paid approximately $40.0 million to Athenex, and the leasehold interest in the Dunkirk Facility was transferred to us. Our annual lease payment will be $2.00 per year for an initial 10-year term, with an option to renew the lease under substantially the same terms and conditions for an additional 10-year term. As part of the transaction, we assumed obligations under various third-party agreements, and committed to spend $1.52 billion on operational expenses during the initial term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. We also committed to hiring 450 employees at the Dunkirk Facility within the first five years following the Commencement Date, with 300 such employees to be hired within the first 2.5 years following the Commencement Date. We are eligible for certain sales-tax exemption savings during the development of the Dunkirk Facility, and certain property tax savings over the next 20 years, subject to certain terms and conditions, including performance of certain of the obligations described above.

In addition, we believe that the Dunkirk Facility has construction needs that may require approximately 12 to 18 months to complete in order for it to be used as intended, and which needs remain as a result of an ongoing dispute with the Dunkirk Facility's general contractor and stay related to Athenex's ongoing bankruptcy proceedings, as described below. Consequently, during the third quarter of 2022, we determined to conduct a reduction-in-force of a significant portion of the then-current employees at the Dunkirk Facility, which became effective in late December 2022. The construction period and reduction-in-force have adversely affected our ability to satisfy certain operational obligations described above, including the initial employee count requirement, which was not timely satisfied and remains unsatisfied, and in addition, while we believe we have complied with all applicable federal and state laws implicated by the reduction-in-force, we could become subject to litigation in connection with these measures.

Failure to satisfy the obligations over the lease term, including the milestones we have committed to achieve, may give rise to certain rights and remedies of the lessor and other governmental authorities including, for example, termination of the lease agreement and other related agreements and potential recoupment of a percentage of the grant funding received by Athenex for construction of the Dunkirk Facility and other benefits received, subject to the terms and conditions of the applicable agreements. In November 2024, we received written notice from our landlord alleging non-compliance with the initial employee count requirement of our lease for the Dunkirk Facility. If we are unable to remedy this alleged default or otherwise reach an acceptable resolution, the landlord may take action to terminate the lease and compel us to surrender the facility, among other remedies. While we are seeking to resolve this matter expeditiously, there can be no assurance that we will succeed in doing so. If we lose access to the Dunkirk Facility and related leased equipment, it could disrupt our operations and planned manufacturing activities, cause us to divert resources to finding alternative facilities, which would not have any subsidies, and could have a significant impact on our operations and financial performance. We may also be subject to lawsuits or claims for damages against us if we are unable to comply with our obligations under these arrangements or in connection with other aspects of the Dunkirk Facility, which could materially and adversely affect our business, results of operations, and financial condition. In addition, we were named as a defendant in a lawsuit filed during the fourth quarter of 2022 by Exyte, the general contractor for the Dunkirk Facility, in New York state court arising from a construction agreement Exyte entered with Athenex pertaining to construction of the Dunkirk Facility. We believe we are entitled to defense costs and indemnification and, accordingly, we have provided notice to Athenex. On May 14, 2023, Athenex, together with certain of its subsidiaries, filed voluntary petitions for relief under Chapter 11 of the United States Bankruptcy Court for the Southern District of Texas. The lawsuit with Exyte has remained stayed as a result of Athenex's bankruptcy proceedings and the construction needs of the Dunkirk Facility remain. The extent of the impact of the Athenex Proceedings and its automatic stay will have on any continuing obligations Athenex may have under the purchase agreement remain unclear. We further believe Exyte's claims against us are without merit, and we intend to defend the claims vigorously. Furthermore, there is no guarantee that the counterparties to our public-private partnerships will comply with the terms of the agreements, including that their ability to fund their capital commitments under the agreements may be subject to their ability to raise additional capital and that further construction or operational timetables may not be met. Public-private partnerships are also subject to risks associated with government and government agency counterparties, including risks related to government relations compliance, sovereign immunity, shifts in the political environment, changing economic and legal conditions and social dynamics.

Our contractors and subcontractors may place liens on our projects, and if they then successfully foreclose on such projects, we may not be able to use such assets for our business.

Under general property law, any contractor or subcontractor doing work on a project may attach a lien on the property with respect to which it does work to secure the dollar value of all labor and material furnished to the project. A valid lien holder could, after the lien is perfected, institute a collection suit, according to the lien, and if it were successful in obtaining a judgment, the real property and the equipment thereon could be foreclosed upon. If a contractor were to successfully foreclose on such liens, we may not then be able to use such assets to manufacture our products, and our business could be materially harmed.

Risks Related to Healthcare and Other Government Regulations

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize our approved product or other product candidates. We are, and will continue to be, subject to ongoing extensive regulation, regulatory obligations and continued regulatory review, which may result in significant additional expense.

Our approved product and other product candidates are subject to extensive governmental regulations relating to, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory review process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, lengthy, time-consuming, uncertain and subject to unanticipated delays and can vary substantially based upon the type, complexity and novelty of the products involved. We had previously received a CRL in response to our initial BLA submission, requiring us to resubmit the BLA to the FDA addressing the issues in the CRL. On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029.

Other than our approved product, we have not submitted any other marketing or drug approval applications to the FDA or comparable foreign authorities for any other product candidate, and we may never receive such regulatory approval for any of our other product candidates or regulatory approval that will allow us to successfully commercialize such other product candidates. In addition, regulatory agencies may lack experience with our technologies and products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other research. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also vary depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our other product candidates.

Any delay in completing development or obtaining, or failing to obtain, required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. 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, be subject to other regulatory enforcement action, and we may not achieve or sustain profitability.

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

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

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our approved product or other product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our approved product or other product candidates will be harmed.

Even though we have received regulatory approval for our approved product, we will continue to be subject to ongoing regulatory requirements concerning it and our other product candidates, which may result in significant additional expenses. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our approved product or other product candidates.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed, or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any approved product, including our current product, will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, including reporting of certain adverse events as well as continued compliance with cGMP for the drug products, and GCP guidelines for any clinical trials that we conduct post-approval.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- holds on clinical trials;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of non-compliance requiring remediation;
- fines, warning or untitled letters;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or withdrawal of product approvals;

- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

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

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful commercializing our approved product or our other product candidates if and when they are approved.

We are in the process of implementing our sales and marketing personnel hiring plan and building out key commercialization infrastructure for the commercialization of our approved product. To achieve commercial success for any other product for which we obtain marketing approval, we may need to hire additional sales and marketing personnel.

We have built, and are continuing to build, a focused sales and marketing infrastructure to market our approved product and potentially other product candidates in the U.S., if and when they are approved, including by partnering with experienced third party contractors. There are risks involved with establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, including failure to receive marketing approval from the FDA, we would have prematurely or unnecessarily incurred these commercialization expenses. For example, we had previously hired sales and marketing personnel for a launch of our now-approved product, but we received a CRL from the FDA in May 2023. We may also inaccurately estimate the number of representatives needed to build our sales force, which may result in unnecessary expense or the inability to scale as quickly as needed. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our approved product and other product candidates, if approved, on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or increase market acceptance of our approved product or any other product candidate, if approved;
- the inability of reimbursement professionals to negotiate arrangements for coverage or adequate reimbursement by payors for our approved product or any other product candidate, if approved;
- the inability to price our approved product or any other product candidates, if approved, at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our approved product or any other product candidates, if approved, to segments of the patient population; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we do not establish sales, marketing and distribution capabilities successfully, we will not be successful in commercializing our approved product or any other product candidates, if approved.

Problems related to large-scale commercial manufacturing could cause delays in product launches, an increase in product costs, product recalls or product shortages.

Manufacturing finished drug products, especially in large quantities, is complex. Our product, and if our other product candidates receive regulatory approval, will require several manufacturing steps and may involve complex techniques to ensure quality and sufficient quantity, especially as the manufacturing scale increases. Our approved product and other product candidates will need to be made consistently and in compliance with a clearly defined manufacturing process pursuant to FDA regulations. Accordingly, it will be essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, filling, labeling, packaging, storage, shipping, quality control and testing, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs. We may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and cause us to fail to satisfy contractual commitments, cause recalls, lead to delays in our clinical trials or result in litigation or regulatory action. Such actions would hinder our ability to meet contractual obligations and could cause material adverse consequences for our business.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we have or may receive and subject us to other penalties that could materially harm our business. For example, our GMP-in-a-Box may be regulated by the FDA as a medical device, and regulatory compliance for medical devices is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate medical devices. All of our potential medical device products and material modifications will be subject to extensive regulation and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution as well as after clearance or approval. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the U.S., a company must first submit a pre-market submission, such as a pre-market notification (510(k)), *De Novo* request, or PMA, and receive clearance, *De Novo* grant, or approval from the FDA, unless an exemption applies.

Any regulatory approvals that we receive for our approved product and other product candidates will require surveillance to monitor the safety and efficacy of the product. The FDA and similar agencies have significant pre- and post-market authority, including requirements related to product design, development, testing, laboratory and preclinical studies, clinical trials approval, manufacturing processes and quality (including suppliers), labeling, packaging, distribution, adverse event and deviation reporting, storage, shipping, pre-market clearance or approval, advertising, marketing, promotion, sale, import, export, product change, recalls, submissions of safety and effectiveness, post-market surveillance and reporting of deaths or serious injuries and certain malfunctions, and other post-marketing information and reports such as deviation reports, registration, product listing, annual user fees, and recordkeeping for our product candidates. The FDA may also require a REMS to approve our product candidates, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The FDA may also require post-approval Phase 4 trials. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval.

Medical devices regulated by the FDA are subject to general controls which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMP under QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; and reporting certain device field removals and corrections to the FDA. In addition to the general controls, some Class 2 medical devices are also subject to special controls. Most medical devices that require pre-market review by the FDA, including most Class 2 medical devices, require the submission of a 510(k) or a *De Novo* request and obtaining 510(k) clearance or *De Novo* grant prior to marketing the device. Some devices known as 510(k)-exempt devices can be marketed without prior clearance or approval from the FDA. Most Class 3 devices are subject to the FDA's PMA requirement. Further, in February 2024, the FDA issued a final rule replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:216 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026.

The FDA can also refuse to clear or approve pre-market submissions for any medical device we develop. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, for any medical device products we develop, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals for any medical device products, they may include significant limitations on the indicated uses for the product, which may limit the market for the product.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance. We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. The cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If the FDA or comparable foreign regulatory authorities become aware of new safety information or previously unknown problems after approval of our approved product or any of our other product candidates, including: (i) adverse events of unanticipated severity or frequency, (ii) that the product is less effective than previously thought, (iii) problems with our third-party manufacturers or manufacturing processes or (iv) failure to comply with regulatory requirements, or if we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may face a number of regulatory consequences, including fines, warnings or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions or partial suspension or total shutdown of production, injunctions, consent decrees, civil penalties and criminal prosecution, among other consequences. Additionally, we may face unanticipated expenditures to address or defend such actions and customer notifications for repair, replacement or refunds. Any such restrictions could limit sales of the product. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

The FDA also regulates the advertising and promotion of medical devices to ensure that the claims are consistent with their regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing, or labeling our medical device products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. If any of our medical device products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations.

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

The FDA prohibits the pre-approval promotion of drugs as safe and effective for the purposes for which they are under investigation. Similarly, the FDA prohibits the promotion of approved drugs for new or unapproved indications. If the FDA finds that we have engaged in pre-approval promotion of our future product candidates, or if our approved product or any of our other product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our approved product and other product candidates, if approved. In particular, an approved product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. However, physicians may nevertheless prescribe our product, or any future approved product, to their patients in a manner that is inconsistent with the approved label, which is within their purview as part of their practice of medicine. If we are found to have promoted such off-label uses, however, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. The FDA may also issue a public warning letter or untitled letter to the company. If we cannot successfully manage the promotion of our product or any future approved products, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Results for any patient who receives compassionate use access to any of our non-approved product candidates should not be viewed as representative of how the product candidate will perform in a well-controlled clinical trial and cannot be used to establish safety or efficacy for regulatory approval.

We often receive requests for compassionate use access to our investigational drugs by patients that do not meet the entry criteria for enrollment into our clinical trials. Generally, patients requesting compassionate use have no other treatment alternatives for life-threatening conditions. We evaluate each compassionate use request on an individual basis, and in some cases grant access to our investigational product candidates outside of our sponsored clinical trials if a physician certifies that the patient receiving treatment is critically ill and does not meet the entry criteria for one of our open clinical trials. Individual patient results from compassionate use access may not be used to support submission of a regulatory application, may not support approval of a product candidate, and should not be considered to be indicative of results from any ongoing or future well-controlled clinical trial. Before we can seek regulatory approval for any of our product candidates, we must demonstrate in well-controlled clinical trials statistically significant evidence that the product candidate is both safe and effective for the indication for which we are seeking approval. The results of our compassionate use program may not be used to establish safety or efficacy or regulatory approval.

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

Our approved product and our other product candidates will be subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the OFAC, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We use CROs abroad for clinical trials. In addition, we may engage third-party intermediaries to sell our approved product or other product candidates and solutions abroad once we enter a commercialization phase for our approved product or such other product candidates and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We have adopted an anti-corruption policy, which mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, there can be no assurance that our employees and third-party intermediaries will comply with this policy or such anti-corruption laws. Non-compliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other investigations, or other enforcement actions. If such actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens.

There is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Our failure to comply with state, national and/or international privacy and security laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

There are numerous laws and regulations at the federal and state levels addressing privacy and security concerns, and some state laws apply more broadly than HIPAA and associated regulations. For example, the CCPA, which went into effect on January 1, 2020, provides, among other things, new privacy and security obligations for covered companies and new privacy rights to California consumers, including the right to opt out of certain sales of their personal information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the CCPA includes limited exceptions, including for certain personal information collected as part of certain clinical trials or other biomedical research studies, it may regulate or impact our processing of personal information depending on the context. Additionally, the CPRA was approved by California voters in November 2020. The CPRA significantly modifies the CCPA, which may require us to modify our practices and policies and may further increase our compliance costs and potential liability. Certain states have also enacted or proposed privacy laws governing health information, including for example, Washington's My Health, My Data Act and Nevada's Senate Bill 370, and all 50 states have enacted laws imposing obligations to provide notification of certain security breaches of personal information. Additionally, several states have enacted or proposed laws similar to the CCPA, such as in New York, Virginia, Colorado, Utah, Connecticut, Iowa, Indiana, Montana, Tennessee, Oregon, Florida, Delaware, and Texas. These laws could mark the beginning of a further trend toward more stringent privacy laws in the U.S. and have prompted a number of proposals for new federal and state-level privacy laws. We cannot yet determine the impact these laws or changes may have on our business and operations, but anticipate they could increase our compliance costs and potential liability, impair our ability to collect, use or otherwise process personal information, expose us to greater liability and require us to modify our practices and policies in an effort to comply.

There are also various laws and regulations in other jurisdictions relating to privacy and security. For example, EU member states and other foreign jurisdictions, including the UK and Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations on us. The collection, use, and other processing of personal data, including patient or health data, in the EU, may be governed by the GDPR. The GDPR, which is wide-ranging in scope and applies extraterritorially, imposes, among other things, requirements relating to the consent of the individuals to whom the personal data relates, the notices provided to such individuals, the security and confidentiality of personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including to the U.S., provides data protection authorities with enforcement authority and imposes large penalties for non-compliance, including the potential for fines of up to €20 million or up to 4% of the total worldwide annual global revenues of the noncompliant entity, whichever is greater. GDPR requirements apply not only to third-party personal data transfers, but also to transfers of personal data between us and our subsidiaries, including employee information. In addition, in January 2021, following its exit from the EU, the UK transposed the GDPR into its domestic law with its own version of the GDPR (combining the GDPR and the UK GDPR), which currently imposes the same obligations as the GDPR in most material respects and provides for fines of up £17.5 million or up to 4% of the total worldwide annual global revenues of the noncompliant entity, whichever is greater.

Complying with numerous, complex, and changing laws and regulations is expensive and difficult. Any actual or alleged failure to comply with any privacy or security law or regulation, or security breach or other incident, including those involving the misappropriation, loss, or other unauthorized use, disclosure or other processing of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third party, could adversely affect our business, financial condition, and results of operations, and could subject us to investigations, litigation, and other proceedings, material fines and penalties, compensatory, special, punitive and statutory damages, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage, and injunctive relief. The enactment of, and changes to, privacy and security laws and regulations have increased our responsibility and potential liability, including in relation to the personal data that we process and our clinical trials, and we may be required to put in place additional mechanisms in an effort to comply with applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, any new law or regulation relating to privacy and security, or any applicable industry standard, may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and security in the U.S., the UK, the EU, and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

We cannot assure you that our CROs or other third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personal information or other sensitive or confidential information will not breach applicable laws or regulations or contractual obligations imposed by us, or that they will not experience security breaches or incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy and security laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that the measures and safeguards we have taken will protect us from the foregoing risks, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We and our third-party contractors must comply with environmental, health and safety laws and regulations. A failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and any of our third-party contract manufacturers or suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, generation, manufacture, storage, treatment and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with such environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability, which could exceed our assets and resources.

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

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts, which could harm our business, prospects, financial condition or results of operations. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Coverage and reimbursement may be limited or unavailable in certain market segments for our approved product or other product candidates, which could make it difficult for us to sell our approved product or other product candidates profitably.

In both domestic and foreign markets, sales of our approved product or other product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Patients are unlikely to use our approved product or other product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our approved product or other product candidates. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In addition, because our approved product and other product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenues from our approved product or other product candidates.

Government authorities and third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. These payors may not view our approved product or other future products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our approved product or other future approved products, if any, to be marketed on a competitive basis. If reimbursement is not available, or is available only to limited levels, our product and other product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our approved product or other product candidates. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. 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 approved product and our other product candidates, if approved, to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is likely to continue, and may result in more or less favorable impacts on pricing. The recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure, while the potential for resulting legislative or policy changes presents uncertainty. Congress has considered and may continue to consider legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases. The impact of these regulations and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is currently unknown. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved product and other product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, federal programs impose penalties on manufacturers of drugs marketed under a BLA or NDA, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. For example, under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our product candidates, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenues and profitability will suffer.

Even if we obtain coverage for a given product, the resulting approved reimbursement payment rates might not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments or achieve or sustain profitability or may require co-payments that patients find unacceptably high. If payors subject our approved product or other product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our approved product or other product candidates. Additionally, if payors require high co-payments, beneficiaries may decline our therapies and seek alternative therapies and physicians may be reluctant to recommend our approved product to their patients. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of physicians and other target customers and third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

We, and our collaborators, cannot be sure that coverage will be available for our approved product or any other product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our approved product or other product candidates if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved product and other product candidates;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. A possible challenge for our approved product and other product candidates arises from the fact that they may potentially be used in an inpatient setting. Inpatient reimbursement generally relies on stringent packaging rules that may mean that there is no separate payment for our approved product or other product candidates. Additionally, data used to set the payment rates for inpatient admissions is usually several years old and would not take into account all of the additional therapy costs associated with the administration of our other product candidates. If special rules are not created for reimbursement for immunotherapy treatments such as our approved product or other product candidates, hospitals might not receive enough reimbursement to cover their costs of treatment, which will have a negative effect on their adoption of our approved product or other product candidates.

Further, the codes used by providers to bill for our approved product could also affect reimbursement. J-codes are codes maintained by the CMS, which are a component of the HCPCS and are typically used to report injectable drugs that ordinarily cannot be self-administered. In October 2024, we were assigned a J-code for ANKTIVA, which will be valid for use beginning on January 1, 2025. To date, we do not have a specific J-code for any of our other product candidates. We cannot guarantee that a J-code will be granted for any of our other product candidates, if approved. To the extent separate coverage or reimbursement is available for our approved candidate or any other product candidates, if approved, and a specific J-code is not available, physicians would need to use a non-specific miscellaneous J-code to bill third-party payors for these physician-administered drugs. Because miscellaneous J-codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim denials and claim errors. As a result, until our J-code for ANKTIVA can be used in 2025, we may experience slower than expected commercial sales.

We may face difficulties from changes to current regulations and future legislation.

In the U.S. 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 approved product or other product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased revenues from our biopharmaceutical product candidates, decreased potential returns from our development efforts, and additional downward pressure on the price that we, or our collaborators, may receive for any approved products.

Since enactment of the ACA in 2010, in both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our approved product or other product candidates profitably. These changes included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. In January 2013, the ATRA was approved which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our approved product or other product candidates, if approved, and accordingly, our financial operations.

Since its enactment, various portions of the ACA have been subject to judicial and constitutional challenges. In June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Any reduction in reimbursement from Medicare or other government healthcare 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 revenues, attain profitability or commercialize our approved product or other product candidates.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities for drugs. 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 approved product or other 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. Recently, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

In addition, there have been increasing legislative efforts and enforcement interest in the U.S. with respect to drug pricing practices, including Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. As discussed above, in August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, future litigation in view of the Supreme Court's overturn of the *Chevron* decision, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, the FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida.

We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current product candidates and any future product candidates or additional pricing pressures.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our product candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably. If reimbursement of our product or other product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, principal investigators, CROs, suppliers and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. As we begin commercializing our approved product and may in the future commercialize our other product candidates, if any, in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct or other improper activities by our employees or third parties that we engage for our business operations and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions, including exclusion from government healthcare programs, and serious harm to our reputation. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs.

Our relationships with health care professionals, institutional providers, principal investigators, consultants, potential customers and third-party payors are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face significant penalties and liabilities.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal FCA. As we begin commercializing our approved product and may in the future commercialize our other product candidates, if any, in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase.

Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to laws of the federal government and state governments in which we conduct our business relating to privacy and security with respect to patient or health data. The laws that may affect our ability to operate include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;

- the U.S. federal false claims and civil monetary penalties laws, including the federal civil FCA, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- HIPAA, which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud healthcare programs, as well as;
- HIPAA, as amended by HITECH, which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of PHI, and requires notification to affected individuals and regulatory authorities of certain breaches of the privacy or security of PHI, and other U.S. laws and foreign laws that govern the privacy or security of health or patient data;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the CMS information related to payments and other transfers of value to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, which is published in a searchable form on an annual basis;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient or health data, privacy or security. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

We expect to incur increased costs of compliance with such laws and regulations as they continue to evolve. If we or our contractors are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal and state health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations. Any of these could adversely affect our business, financial condition, and results of operations.

As we grow our business and expand our sales organization or rely on distributors outside of the U.S., we would be at increased risk of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and the approval of our future BLA submissions, as well as adversely affect the U.S. and global economy and our liquidity, financial condition and earnings.

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 and related government shutdowns, the ability to hire and retain key personnel and accept the payment of user fees, 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 the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including disruptions due to public health concerns, resurgence of COVID-19 cases, travel restrictions, or staffing shortages, may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs in the future, including as a result of any failure by the U.S. federal government to increase the debt ceiling, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, as well as cause interest rates and borrowing costs to further increase, which may negatively impact our ability to access the debt markets, including the corporate bond markets, on favorable terms, which could have a material adverse effect on our business, financial condition and results of operations and/or our BLA submissions.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our approved product and other product candidates and technologies, we may not be able to compete effectively or operate profitably and may lose our ability to prevent our competitors from commercializing similar or identical technology and our approved product and other product candidates would be adversely affected.

Our success is dependent in large part on our obtaining, maintaining, protecting and enforcing patents and other proprietary rights in the U.S. and other countries with respect to our approved product and other product candidates and technology and on our ability to avoid infringing the intellectual property and other proprietary rights of others. Certain of our intellectual property rights are licensed from other entities, and as such the preparation and prosecution of any such patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and has been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. As a result, the issuance, scope, validity, enforceability, or commercial value of our patent rights remain highly uncertain.

Any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing therapeutics and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, any of our issued or granted patents will not later be found to be invalid or unenforceable, or any issued or granted patents will include claims sufficiently broad to cover our product candidates and technology, or to provide meaningful protection from our competitors. Our owned or in-licensed pending and future patent applications may not result in patents being issued that protect our ANKTIVA, hAd5, saRNA and yeast technologies and constructs, cell-based therapies or other product candidates and technologies or that effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our ANKTIVA, hAd5, saRNA and yeast technologies and constructs, cell-based therapies or other product candidates and technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and it is uncertain how much protection, if any, will be provided by our patents, including if they are challenged in the courts or patent offices or in other proceedings, such as re-examinations or oppositions, which may be brought in the U.S. or foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, it is possible that competitors may infringe our patents or successfully avoid the patented technology through design innovation. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, even if we were successful in stopping the violation of our patent rights.

We or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we, or one of our licensors, may be required to participate in interference proceedings in the USPTO to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the U.S., or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the first-inventor-to-file law in the U.S. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may also be required to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, which challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of patent protection of our ANKTIVA, hAd5, saRNA and yeast technologies and constructs, cell-based therapies or other product candidates and technologies. For example, the validity of one of our European patents, EP Patent No. 3601363, is being challenged in an opposition proceeding. This patent is directed to methods of using ANKTIVA-based combination therapy with anti-CD38 antibodies to treat cancer, which does not directly relate to any of our current programs. We intend to defend our patent and believe we have meritorious defenses against this opposition. An adverse determination in any of the type of submissions described above, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our ANKTIVA, hAd5, saRNA and yeast technologies and constructs, cell-based therapies or other product candidates or technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

If we or our collaborators are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to cease using the technology or to obtain and maintain license rights from prevailing third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. A prevailing party in that case may not offer us a license on commercially acceptable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. In addition, certain of our licensors co-own the patents and patent applications we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

We or our licensors, collaborators, or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other intellectual property or the patents or other intellectual property of our licensors, all of which could be expensive, time-consuming and unsuccessful, may delay or prevent the development and commercialization of our product candidates, or may put our patents and other proprietary rights at risk.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or other technologies, the defendant could counterclaim that the patent is invalid and/or unenforceable or that we infringe their patents. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or other applicable body, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our licensor, our or our licensor's patent counsel and the patent examiner were unaware during prosecution. Moreover, even if our patents were to survive such a litigation challenge to their validity, the patents might still be held to be valid but unenforceable if a court were to decide that the patents are being enforced in a manner inconsistent with the antitrust laws, or that the patents were obtained through deceit during patent office examination or other such failure of sufficient candor to the patent office. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects. The validity of one of our European patents, EP Patent No. 3601363, is being challenged in an opposition proceeding. We intend to defend our patent and believe we have meritorious defenses against this opposition.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources, including our scientists and management, from our business.

An adverse result in any litigation or defense proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and could put our patent applications at risk of not being issued. Such proceedings could result in revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover our product candidates or technologies. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. In addition, in an infringement proceeding, there is a risk that a court may decide that one or more of our patents is not valid or is unenforceable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the grounds that its activities are not covered by, that is, do not infringe, our patents. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be better able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

The use of our technology and product or our other product candidates could potentially conflict with the rights of others, and third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product, product candidates and technologies.

Our commercial success depends in part on our, our licensors' and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biopharmaceutical industry. Our potential competitors or other parties may have, develop or acquire patent or other intellectual property rights that they could assert against us. If they do so, then we may be required to alter our approved product or other product candidates, pay licensing fees or cease our development and commercialization activities with respect to the applicable approved product or product candidates or technologies. If our approved product or other product candidates conflict with patent or other intellectual property rights of others, such parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing, use and marketing of the affected products.

Although we have conducted FTO analyses of the patent landscape with respect to our approved product or other product candidates and continue to undertake FTO analyses of our manufacturing processes, no FTO analysis can be considered exhausted because patent applications do not publish for 18 months and the claims of patent applications can change over time. We may not be aware of patents that have already been issued and that a competitor or other third party might assert are infringed by our approved product or other product candidates or technologies. It is also possible that we could be found to have infringed patents owned by third parties of which we are aware, but which we do not believe are relevant to our approved product or other product candidates or technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our approved product or other product candidates or technologies may infringe. Furthermore, patent and other intellectual property rights in biotechnology remains an evolving area with many risks and uncertainties. As such, we may not be able to ensure that we can market our approved product or other product candidates without conflict with the rights of others.

If intellectual property-related legal actions asserted against us are successful, in addition to any potential liability for damages (including treble damages and attorneys' fees for willful infringement), we could be enjoined from, or required to obtain a license to continue, manufacturing, promoting the use of or marketing the affected products. We may not prevail in any legal action and a required license under the applicable patent or other intellectual property may not be available on acceptable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be required to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our approved product and other product candidates.

As is the case with other immunotherapy and biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the America Invents Act enacted in September 2011, the U.S. transitioned to a first-to-file system in which, assuming that other requirements for patentability are

met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before such third party made it. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our product candidates or other technologies or invent any of the inventions claimed in our or our licensor's patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened 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 decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned or licensed by us will be found invalid based on the foregoing, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensors to pay these fees and take the necessary actions to comply with these requirements. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse impact on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates and technologies are subject, in part, to the terms and conditions of licenses granted to us by others.

We will rely on licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of products enabled by our adenoviral, saRNA and yeast (including Tarmogen) vaccine technologies.

License agreements may not provide exclusive rights to use certain licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to commercialize our technology and product candidates in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that also utilize technology that we have in-licensed.

In addition, subject to the terms of any such license agreements, we do not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that our in-licensed or out-licensed patents and patent applications that are controlled by our licensors or licensees will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors or licensees fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize our approved product and any of our product candidates that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, certain of our in-licensed intellectual property was funded in part by the U.S. government. As a result, the U.S. government may have certain rights to such intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. in certain circumstances if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and growth prospects.

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

We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates. We may be unable to obtain certain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product or product candidates or continue to utilize our existing technology, which could harm our business, financial condition, results of operations and growth prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In addition, each of our license agreements, and we expect our future agreements, will impose various development, diligence, commercialization, and other obligations on us. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our commercialization of our approved product or the development and commercialization of certain of our other product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

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

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

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

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights in various jurisdictions throughout the world.

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

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

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

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed trade secrets or other confidential information of third parties or claims asserting ownership of what we regard as our own intellectual property.

We have received confidential and proprietary information from third parties and their employees and contractors. In addition, we plan to employ and contract with individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed the trade secrets or other confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against or pursue these claims. Even if we are successful in resolving these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

An element of our intellectual property strategy is to license intellectual property rights and technologies from third parties and/or our affiliates. Other parties, including our competitors or our affiliates, may have patents relevant to our business, may have already filed patent applications relevant to our business, and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. In addition, with respect to any patents we co-own with other parties, including our affiliates, we may require licenses to such co-owners' interest to such patents. The licensing or acquisition of intellectual property rights is a competitive area, and other more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties and/or our affiliates. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future additional product candidates and could increase the cost, and extend the timelines associated with our development, of such other products, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for our approved product or any other product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, including our approved product, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended per new drug, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the U.S. and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of

relevant patents, or otherwise failing to satisfy applicable requirements. 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 shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and growth prospects could be materially harmed.

We may be subject to claims challenging rights in our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property, including as an inventor or co-inventor. For example, we or our licensors may have disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship, or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

In addition to seeking patents for ANKTIVA, hAd5, saRNA and yeast technologies and constructs, cell therapies, and other product candidates and technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our approved product or other product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Common Stock and CVRs

Dr. Soon-Shiong, our Founder, Executive Chairman, Global Chief Scientific and Medical Officer and principal stockholder, has significant interests in other companies which may conflict with our interests.

Our Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, is the founder of NantWorks. The various NantWorks companies are currently exploring opportunities in the immunotherapy, oncology, infectious disease, and inflammatory disease fields. In particular, we have agreements with a number of related parties that provide services, technology and equipment for use in their efforts to develop their product pipelines. Dr. Soon-Shiong holds a controlling interest, either directly or indirectly, in these entities. Consequently, Dr. Soon-Shiong's interests may not be aligned with our other stockholders, and he may from time to time be incentivized to take certain actions that benefit his other interests and that our other stockholders do not view as being in their interest as investors in our company. In addition, other companies affiliated with Dr. Soon-Shiong may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in other therapeutic fields which we may target in the future). Moreover, even if they do not directly relate to us, actions taken by Dr. Soon-Shiong and the companies with which he is involved could impact us.

We are also pursuing supply arrangements for various investigational agents controlled by affiliates to be used in their clinical trials. If Dr. Soon-Shiong were to cease his affiliation with us or NantWorks, these entities may be unwilling to continue these relationships with us on commercially reasonable terms, or at all, and as a result may impede our ability to control the supply chain for our combination therapies. These collaboration agreements do not typically specify how sales will be apportioned between the parties upon successful commercialization of the product. As a result, we cannot guarantee that we will receive a percentage of the revenues that is at least proportional to the costs that we will incur in commercializing the product candidate.

We have entered into shared services agreements with NantWorks, pursuant to which NantWorks and its affiliates provide corporate, general and administrative and other support services to us. If Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, we may be unable to establish or maintain this relationship with NantWorks on a commercially reasonable basis, if at all. As a result, we could experience a lack of business continuity due to loss of historical and institutional knowledge and a lack of familiarity of new employees and/or new service providers with business processes, operating requirements, policies and procedures, and we may incur additional costs as new employees and/or service providers gain necessary experience. In addition, the loss of the services of NantWorks might significantly delay or prevent the commercialization of our approved product or the development of our other product candidates or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business and results of operations.

Dr. Soon-Shiong, through his voting control of the company, has the ability to control actions that require stockholder approval.

Dr. Soon-Shiong, through his direct and indirect ownership of the company's common stock, has voting control of the company. As of September 30, 2024, Dr. Soon-Shiong and his affiliates own approximately 76.4% of the company's common stock outstanding. Dr. Soon-Shiong and his affiliates also own all of our outstanding convertible promissory notes, certain warrants and stock options to purchase shares of our common stock, and certain CVRs as described under "—Conversion of certain related-party promissory notes, exercise of outstanding warrants and options to purchase our common stock, the achievement of the milestone under our outstanding CVRs, and potential additional equity issuances may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock" below.

Dr. Soon-Shiong is in a position to control the outcome of corporate actions that require, or may be accomplished by, stockholder approval, including amending the bylaws of the company, the election or removal of directors and transactions involving a change of control. Dr. Soon-Shiong's controlling ownership could limit the ability of the remaining stockholders of the company to influence corporate matters, and the interests of Dr. Soon-Shiong may not coincide with the company's interests or the interests of its remaining stockholders.

In addition, pursuant to the Nominating Agreement between us and Cambridge, an entity that Dr. Soon-Shiong controls, Cambridge has the ability to designate one director to be nominated for election to the Board of Directors for as long as Cambridge continues to hold at least 20% of the issued and outstanding shares of our common stock. Dr. Soon-Shiong was selected by Cambridge to hold this board seat. Dr. Soon-Shiong and his affiliates will therefore have significant influence over management and significant control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions, such as a merger or other sale of our company or its assets, for the foreseeable future. This control will limit stockholders' ability to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected.

Conversion of certain related-party promissory notes, exercise of outstanding warrants and options to purchase our common stock, the achievement of the milestone under our outstanding CVRs, and potential additional equity issuances may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock.

As of September 30, 2024, the company had outstanding promissory notes representing an aggregate of $610.0 million principal amount held by entities affiliated with Dr. Soon-Shiong that are convertible into shares of our common stock under certain circumstances, including the following:

- a $380.0 million principal amount of Tranche 2 of our convertible promissory note due December 31, 2025 bearing interest at 3-month Term SOFR plus 7.5% per annum, which provides that the noteholder has the sole option to convert all (but not less than all) of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $8.2690 per share (subject to appropriate adjustment from time to time for any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification, or other similar event);

- a $200.0 million principal amount convertible promissory note due September 11, 2026 bearing interest at 1-month Term SOFR plus 8.0% per annum provides that the noteholder has the sole option to convert all (but not less than all) of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $1.9350 per share (subject to appropriate adjustment from time to time for any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification, or other similar event); and
- a $30.0 million principal amount convertible promissory note due December 31, 2025 bearing interest at 3-month Term SOFR plus 8.0% per annum, which provides that the noteholder has the sole option to convert all (but not less than all) of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $2.28 per share (subject to appropriate adjustment from time to time for any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification, or other similar event).

In addition, as of September 30, 2024, we had outstanding warrants, stock options and unvested RSU awards covering the issuance of up to:

- 9,090,909 shares of our common stock at an exercise price of $6.60 per share, which are currently exercisable with an expiration date of December 12, 2024 (these warrants were issued to certain institutional investors);
- 6,399,171 shares of our common stock at an exercise price of $3.2946 per share, which are currently exercisable with an expiration date of July 24, 2026 (these warrants were issued to certain institutional investors);
- any shares of our common stock that may be issued upon the exercise of the $5.0 million option held by Oberland, for which the price per share shall be determined by the 30-day trailing volume weighted-average price of our common stock, calculated from the date of exercise, and which option is exercisable by Oberland until the earliest of (i) December 29, 2028, (ii) a change of control of the company, or (iii) a sale of substantially all of the company's assets;
- 3,162,648 stock options and RSU awards issued to Dr. Soon-Shiong that are outstanding as of September 30, 2024, of which 1,392,730 are vested and exercisable and 1,769,918 are unvested and unexercisable; and
- 1,638,000 shares of our common stock at an exercise price of $3.24 per share exercisable from the 30th day following the achievement of a performance-based vesting condition pertaining to building manufacturing capacity to support supply requirements for one of our product candidates (which has not yet been satisfied) with an expiration date on the tenth anniversary of such initial exercise date (this warrant was issued to an affiliate of Dr. Soon-Shiong).

In addition, as of September 30, 2024, we had outstanding an aggregate of approximately $300.6 million of CVRs issued to the former stockholders of Altor, including Dr. Soon-Shiong and certain affiliates, which such stockholders may choose to receive either in cash or shares of our common stock based upon an average of closing prices on a 20-trading day trailing period, upon the first calendar year prior to December 31, 2026 in which worldwide net sales of ANKTIVA exceed $1.0 billion. ANKTIVA is now approved for commercial sale with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, but there can be no assurance that such sales milestone will be achieved. Dr. Soon-Shiong and his related party hold approximately $139.8 million of such CVRs, and have irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs.

The conversion or exchange of some or all of our outstanding promissory notes into shares of our common stock, the exercise of any of our outstanding warrants and stock options, and the decision of the holders of our CVRs to receive shares of our common stock could dilute the ownership interests of existing stockholders. Any sales in the public market of our outstanding promissory notes or warrants, or our common stock issuable upon conversion of the promissory notes or exercise of the warrants or options, could adversely affect prevailing market prices of our common stock.

The market price of our common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.

Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- the commencement, enrollment or results of the planned clinical trials of our non-FDA-approved product candidates or any future clinical trials we may conduct, or changes in the development status of such product candidates;
- any delay in our regulatory submissions for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such submissions, including without limitation the FDA's issuance of a CRL or a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our approved product or other product candidates, including but not limited to clinical trial requirements for approvals;
- our failure to commercialize our approved product or other product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our approved product or other product candidates;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- our ability to effectively manage our growth;
- variations in our quarterly operating results, including those driven by liability accounting associated with embedded derivatives;
- our liquidity position, RIPA liability covenants and the amount and nature of any debt we may incur;
- announcements that our revenue or income are below or that costs or losses are greater than analysts' expectations;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- sales of large blocks of our common stock;
- fluctuations in stock market prices and volumes;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;

- the perception of our clinical trial results by retail investors, which investors may be subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet;
- general economic slowdowns;
- government-imposed lockdowns, supply chain disruptions, and adverse economic effects from a potential pandemic, epidemic, or outbreak of an infectious disease, in the U.S. and abroad;
- geopolitical tensions and war, including the war in Ukraine and ongoing conflicts in Gaza and Yemen;
- coordinated actions by independent third-party actors to affect the price of certain stocks, coordinated via the internet and otherwise; and
- other factors described in this "*Risk Factors*" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

We are currently subject to securities class action litigation and other litigation and may be subject to similar or other litigation in the future, all of which will require significant management time and attention, result in significant legal expenses and may result in unfavorable outcomes, which may have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock.

We are, and may in the future become, subject to various legal proceedings and claims that arise in or outside the ordinary course of business. For example, on June 30, 2023, a putative securities class action complaint, captioned *Salzman v. ImmunityBio, Inc. et al.* , No. 3:23-cv-01216-BEN-WVG, was filed in the U.S. District Court for the Southern District of California against the company and three of its officers and/or directors, asserting violations of Sections 10(b) and 20(a) of the Exchange Act stemming from the company's disclosure on May 11, 2023 that it had received an FDA CRL stating, among other things, that it could not approve the company's original BLA submission in its initial form due to deficiencies related to its pre-license inspection of the company's third-party CMOs. The complaint alleges that the defendants had previously made materially false and misleading statements and/or omitted material adverse facts regarding its third-party CMOs and the prospects for regulatory approval of the BLA. The complaint did not specify the amount of damages being sought. On September 27, 2023, the court appointed a lead plaintiff, approved their selection of lead counsel, and re-captioned the case *In re. ImmunityBio, Inc. Securities Litigation,* No. 3:23-cv-01216. On November 17, 2023, the lead plaintiff filed an amended complaint, which named the same defendants and asserted the same claims as the previous complaint. On January 8, 2024, the defendants filed a motion to dismiss the amended complaint. On June 20, 2024, the court issued an order granting in part and denying in part the motion to dismiss. On July 16, 2024, the lead plaintiff notified the court that he would proceed with his current pleading, and the defendants answered the complaint on August 29, 2024. In addition, on October 29, 2024, a shareholder derivative action was filed in the U.S. District Court for the Southern District of California against the members of our Board of Directors and certain officers, captioned *Van Luven v. Soon-Shiong et al.*, Case No. 3:24-cv-02014-L-AHG. Stemming from the company's May 11, 2023 disclosure that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the derivative complaint alleges that the individual defendants authorized or permitted materially false and misleading statements and/or omitted material adverse facts regarding ImmunityBio's third-party CMOs and the prospects for regulatory approval of the ANKTIVA BLA. See Item 1. "*Legal Proceedings*" for more information.

The results of the securities class action lawsuit, the derivative action and any future legal proceedings cannot be predicted with certainty. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into a settlement arrangement in connection with such claim. Any such payments or settlement arrangements in current or future litigation could have a material adverse effect on our business, operating results, or financial condition. Even if the plaintiffs' claims are not successful, current or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock. In addition, such lawsuits may make it more difficult to finance our operations.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell substantial amounts of our common stock in the public market, including shares obtained from the conversion or exchange of our convertible promissory notes, exercise of our warrants, satisfaction of our CVRs, or the exercise or settlement of our equity incentive awards, the market price of our common stock could decline significantly. In addition, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, and his affiliates owned approximately 76.4% of our outstanding shares of common stock as of September 30, 2024. Sales of stock by Dr. Soon-Shiong and his affiliates could have an adverse effect on the trading price of our common stock.

Certain holders of our common stock are entitled to certain rights with respect to the registration of their shares under the Securities Act, including the shares purchased by affiliates of Oberland in connection with our entry into the RIPA. 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 held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have an adverse effect on the market price of our common stock.

In addition, we expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, regulatory approval efforts, pre-commercialization and commercialization activities, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, including as part of the ATM, convertible securities, or other equity securities (including warrants) in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, existing investors may be materially diluted, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock. The issuance of additional shares of common stock or warrants to purchase common stock, perception that such issuances may occur, or the exercise of outstanding warrants or other equity securities will have a material dilutive impact on existing stockholders and could have a material negative effect on the market price of our common stock.

We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

As a public company listed in the U.S., we have incurred and will continue to incur significant additional legal, accounting, and other expenses as a result of operating as a public company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including Sarbanes-Oxley and regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to create a larger finance function with additional personnel to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. As of June 30, 2024, the market value of our common stock held by non-affiliates exceeded $700.0 million. Consequently, we will be a large accelerated filer and will therefore cease to be a smaller reporting company effective December 31, 2024 and will no longer be able to rely on the scaled disclosure exemptions available to smaller reporting companies starting with our Quarterly Report on Form 10-Q for the three months ending March 31, 2025. As a result of this transition, we will be subject to certain disclosure and compliance requirements that apply to other public companies which did not previously apply to us due to our status as a smaller reporting company and expect to incur additional legal and financial compliance costs as a result.

As a public company in the U.S., we are required, pursuant to Section 404 of Sarbanes-Oxley to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting, and in connection with our transition to being a large accelerated filer, we expect that compliance with the auditor attestations requirements of Section 404(b) of the Sarbanes-Oxley Act beginning with the Annual Report on Form 10-K for the year ended December 31, 2024 will substantially increase our compliance costs. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

In the normal course of business our controls and procedures may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or Nasdaq, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and investors could lose confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

Operating as a public company makes it more expensive for us to obtain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on the Board of Directors, on committees of the Board of Directors, or as members of senior management.

If a restatement of our consolidated financial statements were to occur, our stockholders' confidence in the company's financial reporting in the future may be affected, which could in turn have a material adverse effect on our business and stock price.

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to restate our financial results. In addition, if we are unable to successfully remediate any future material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends for the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition, and other business and economic factors affecting us at such time as the Board of Directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Because we are relying on the exemptions from corporate governance requirements as a result of being a "controlled company" within the meaning of the Nasdaq listing standards, you do not have the same protections afforded to stockholders of companies that are subject to such requirements.

Our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, and entities affiliated with him, control a majority of our common stock. As a result, we are a controlled company within the meaning of the Nasdaq listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a controlled company and may elect not to comply with certain Nasdaq corporate governance requirements, including (1) the requirement that a majority of the Board of Directors consist of independent directors and (2) the requirement that we have a Nominating and Corporate Governance Committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. Accordingly, you do not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements. However, our Board of Directors is currently comprised of a majority of independent directors, and we currently have a Nominating and Corporate Governance Committee and the majority of the members of such committee are independent directors.

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

The trading market for our common stock and the value of our warrants will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts' cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Holders of our CVRs that are payable contingent upon us achieving certain milestones may not receive any further consideration.

In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026. ANKTIVA with BCG is now approved for commercial sale for the treatment of adult patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, but there can be no assurance that such sales milestone will be achieved. Accordingly, holders of our CVRs that are payable contingent upon us achieving the aforementioned milestone may not receive any further consideration.

We are not subject to the provisions of Section 203 of the DGCL, which could negatively affect your investment.

We elected in our Amended and Restated Certificate of Incorporation to not be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes a merger, asset sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. Our decision not to be subject to Section 203 will allow, for example, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer (who, with members of his immediate family and entities affiliated with him, owned, in the aggregate, approximately 76.4% of our common stock as of September 30, 2024) to transfer shares in excess of 15% of our voting stock to a third-party free of the restrictions imposed by Section 203. This may make us more vulnerable to takeovers that are completed without the approval of our Board of Directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders. These provisions include:

- a requirement that special meetings of stockholders be called only by the board of directors, president or chief executive officer;
- advance notice requirements for stockholder proposals and nominations for election to the board of directors; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

These anti-takeover provisions and other provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by the then-current Board of Directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline.

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 DGCL, 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 are not 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 bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

(a) Recent Sales of Unregistered Securities

None.

(b) Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

(c) Adoption and Termination (including Modification) of Rule 10b5-1 and Certain Other Trading Arrangements by Directors and Officers

On September 4, 2024 , Dr. Barry J. Simon , a member of our board of directors and our Chief Corporate Affairs Officer , adopted a written plan for the sale of up to 3,262,417 shares of our common stock that is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. The plan will expire on June 3, 2026 , or on any earlier date on which all of the shares have been sold.

ITEM 6. EXHIBITS.

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

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. (incorporated by reference to Exhibit 3.1 to company's Current Report on Form 8-K filed with the SEC on August 4, 2015).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. dated March 9 (incorporated by reference to Exhibit 3.1 to the company's Current Report on Form 8-K filed with the SEC on March 10, 202
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. dated February 1, 2022 (incorporated by reference to Exhibit 3.3 to the company's POSASR filed with the SEC on March 1, 2022)
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. dated October 18, 2023 (incorporated by reference to Exhibit 3.4 to the company's Quarterly Report on Form 10-Q filed with the S November 9, 2023).
3.5	Amended and Restated Bylaws of ImmunityBio, Inc. effective as of March 10, 2021 (incorporated by reference to Exhibit 3.2 to the company's Quarterly Report on Form 10-Q filed with SEC on August 12, 2021).
10.1*+	Settlement Agreement and Release dated July 13, 2024 entered into by and among Altor BioScience, LLC, NantCe Inc., HCW Biologics, Inc., and Dr. Hing C. Wong
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a) of the Securi Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a) of the Securiti Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Filed herewith.

** The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report are deemed furnished and not filed with the SEC and are not to be incorporated by reference into any filing of ImmunityBio, Inc. under the Securities Act or the Exchange Act, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

+ Some information, schedules and exhibits have been redacted pursuant to Item 601of Regulation S-K. The company agrees to furnish to the SEC a copy of any redacted information upon request.

SIGNATURES

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

IMMUNITYBIO, INC.
Registrant

Date: November 12, 2024

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 10.1

CERTAIN INFORMATION HAS BEEN REDACTED FROM THIS EXHIBIT IN ACCORDANCE WITH ITEM 601(B)(10)(IV) OF REGULATION S-K BECAUSE SUCH INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE OF INFORMATION THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT HAS BEEN SO REDACTED FROM THIS EXHIBIT HAS BEEN MARKED WITH "[*****]" TO INDICATE THE OMISSION.

SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement and Release dated July 13, 2024 ("Settlement" or "Agreement") is made and entered into by and among the following parties and by and through their respective counsel: (i) Altor BioScience, LLC ("Altor"), (ii) NantCell, Inc. ("NantCell" and, together with Altor, "Claimants"), (iii) HCW Biologics, Inc. ("HCW"), and (iv) Dr. Hing C. Wong ("Dr. Wong" and, together with HCW, "Respondents," and Respondents, together with Claimants, the "Settling Parties"). The parties to this Agreement are referred to herein collectively as the "Parties" and each a "Party." The Settlement is intended by the Settling Parties to fully, finally, and forever resolve, discharge, and settle the Settled Claims subject to the terms and conditions hereof.

I. BRIEF OVERVIEW OF THE CLAIMS

a. On December 23, 2022, Dr. Wong filed a statement of claims against Claimants in JAMS Arbitration for declaratory relief, seeking a declaration that Dr. Wong was not liable to Claimants for breach of contract and other causes of action.[1]

[1] *Dr. Hing C. Wong v. Altor BioScience, LLC; NantCell, Inc.* JAMS Arbitration Ref. No. [*****].

b. Also on December 23, 2022, Claimants filed suit against HCW in the District Court for the Southern District of Florida for misappropriation of trade secrets and other causes of action.[2]

c. On January 9, 2023, Claimants filed a demand for arbitration against Dr. Wong in JAMS Arbitration for breach of contract and other causes of action.[3]

d. On May 1, 2023, Claimants filed a demand for arbitration against HCW for misappropriation of trade secrets and other causes of action.[4]

e. Ultimately, the federal action was dismissed in favor of the three arbitrations, which were consolidated into one action, referred to as JAMS Reference No. [*****].

f. On April 1, 2024, Claimants filed an action against HCW in the Court of Chancery of the State of Delaware.[5]

[2] *Altor BioScience, LLC., et al., v. HCW Biologics, Inc.,* Case No. 22-CV-62404-RAR (S.D. Fla. Dec. 23, 2022).
[3] *Altor BioScience, LLC., NantCell, Inc. v. Hing C. Wong,* JAMS Arbitration Ref. No [*****].
[4] *Altor BioScience, LLC., NantCell, Inc. v. HCW Biologics,* JAMS Arbitration Ref. No. [*****].
[5] *Altor BioScience, LLC., and NantCell, Inc. v. HCW Biologics, Inc.,* C.A. No. 2024-310-PAF (Del. Ch. Apr. 1, 2024).

II. CLAIMS OF CLAIMANTS AND BENEFITS OF SETTLEMENT; RESPONDENTS DENIAL OF WRONGDOING AND LIABILITY

The Settling Parties wish to settle the Actions solely as between the Claimants, on the one hand, and Respondents, on the other hand, by entering into this Settlement, solely to avoid the costs, disruption, and distraction of further litigation, and without admitting the validity of any allegations made in the Actions, or any liability with respect thereto, have concluded that it is desirable that the claims against them be settled and dismissed on the terms reflected in this Settlement. Further, entry into this Settlement by Claimants is not an admission as to the lack of merit of any of the claims asserted by any of them in the Actions, and entry into this Settlement by Respondents is not an admission as to the merit of any of the claims asserted against them in the Actions.

III.TERMS OF SETTLEMENT AGREEMENT AND RELEASE

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged and agreed, the Parties hereby agree as follows:

1. **Definitions.** As used in this Settlement, the following terms have the meanings specified below.

(a) “Actions” refer to the civil litigation and arbitrations referenced in Section I above.

(b) “Active Ingredient” means any clinically active material that provides pharmacological activity in a pharmaceutical product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies).

(c) “Additional Molecule” means any fusion protein developed by HCW utilizing the TOBI Platform as of the Effective Date other than the TGFb Molecules. Notwithstanding the foregoing, “Additional Molecule” specifically excludes HCW9302.

(d) “Affiliate” means any Person that Controls, is Controlled by, or is under common Control with another Person.

(e) [*****].

(f) “Cellular Therapy Products” means any pharmaceutical or biological product, process or therapy that contains or comprises cells (including without limitation, cytokine-induced memory-like Natural Killer Cells or T-Cells) that have been engineered, modified, or otherwise manipulated ex vivo, as an Active Ingredient, either alone or in combination with other Active Ingredients.

Notwithstanding the foregoing, for purposes of this Agreement, Cellular Therapy Products shall not include Treg Products.

(g) "cGMP" means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable applicable law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the United States, including the quality guidelines promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical ingredients" and the regulations promulgated thereunder, in each case as they may be updated from time to time.

(h) "CMC" means chemistry, manufacturing and controls processes with respect to any product or investigational agent, including the chemistry, manufacturing and controls section of any regulatory materials for such product or investigational agent.

(i) "Commercialization" means any and all activities, other than manufacturing, directed to the preparation for sale of, or sale of the referenced products, including activities related to marketing, promoting, distributing, and importing the products, and interacting with Regulatory Agencies regarding any of the foregoing. When used as a verb, "to Commercialize" and "Commercializing"

means to engage in Commercialization, and “Commercialized” has a corresponding meaning.

(j) “Control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a Person, whether through the ability to exercise voting power, by contract or otherwise provided that with respect to any Intellectual Property Rights or information, “control” means that the applicable Person owns or has a license to such item or right and has the ability to grant to a party a license, sublicense, or rights of access and use under such item or right without (a) violating the terms or conditions of any agreement or other arrangement between such Person and any Third Party in existence as of the time such party would be required hereunder to grant such license, sublicense, or rights of access and use, and (b) paying any consideration to any Third Party. “Controlling” and “Controlled” have meanings correlative thereto.

(k) “Development” means (i) with respect to ImmunityBio, all activities related to discovery, research, development, creation and prosecution of Intellectual Property Rights, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval

Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Agency as a condition or in support of obtaining or maintaining a Regulatory Approval and (ii) with respect to HCW, all activities related to discovery, research, development, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, clinical studies, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Agency as a condition or in support of obtaining or maintaining a Regulatory Approval and, solely with respect to Non-TGFb Products, subject to ImmunityBio's rights under Paragraphs 2(d), 2(e), 2(f) or 5(e), all activities related to the creation and prosecution of Intellectual Property Rights generated after the Effective Date (other than with respect to a Non-TGFb Product in the Oncology Field that is Directed To a Licensed Target created by either Party utilizing the TOBI Platform). When used as a verb, "Develop" means to engage in Development.

(l) "Directed To" means, with respect to any fusion protein, molecule and/or antibody and a biological target and/or its receptor or Licensed Target, that such fusion protein, molecule and/or antibody binds to, inhibits,

modulates or otherwise interacts with such biological target and/or its receptor or Licensed Target.

(m) “Drug Approval Application” means a New Drug Application submitted pursuant to Section 505 of the FD&C Act, a Biologics License Application, or any corresponding foreign application (in each case, including any amendment or supplement thereto) for any investigational agent.

(n) “Effective Date” means the date of full execution of this Settlement by all of the Settling Parties.

(o) “EirGenix” means EirGenix, Inc.

(p) “Exclusive Licensed Field” means (i) with respect to TGFb Products covered by Group A Patents, Group B Patents or HCW Additional Assigned Patents, all Indications other than those in the Oncology Field and (ii) with respect to Non-TGFb Products covered by Group B Patents or HCW Additional Assigned Patents, all Indications other than neoadjuvant ovarian cancer Indications. For clarity, the “Exclusive Licensed Field” for Licensed Products that contain both TGFb Molecules and non-TGFb molecules shall be limited to Indications other than those in the Oncology Field.

(q) “Exploit” or “Exploitation” means (i) with respect to ImmunityBio, the making, having made, using, having used, selling, having sold, offering for sale or otherwise disposing of, a product or investigational agent,

including all discovery, research, Development (including the conduct of clinical trials), manufacturing, registration, modification, enhancement, improvement, labeling, storage, formulation, exportation, importation, optimization, transportation, distribution, promotion, marketing and Commercialization activities related thereto and (ii) with respect to HCW, using, having used, selling, having sold, offering for sale or otherwise disposing of, a product or investigational agent, including all discovery, research, Development (including the conduct of clinical trials), registration, labeling, storage, exportation, importation, transportation, distribution, promotion, marketing and Commercialization activities related thereto and, solely with respect to Non-TGFb Products (other than any Non-TGFb Product that is Directed To a Licensed Target created by either Party utilizing the TOBI Platform) and any product exclusively licensed by HCW to Wugen under the Wugen Agreement as of the Effective Date, the making or having made of a product or investigational agent and all manufacturing, modification, enhancement, improvement, formulation, and optimization activities related thereto.

(r) “FDA” means the United States Food and Drug Administration or any successor federal agency thereto.

(s) “Group A Patents” means the Group A Patent Rights as set forth in **Schedule 1** and all Patent Rights thereof and thereto.

(t) “Group B Patents” means the Group B Patent Rights as set forth in **Schedule 1** and all Patent Rights thereof and thereto.

(u) “Group C Patents” means the Group C Patent Rights as set forth in **Schedule 1** and all Patent Rights thereof and thereto.

(v) “ImmunityBio” means ImmunityBio, Inc., a Delaware corporation.

(w) “Improvements” means any improvements, enhancements or modifications to the products developed using the TOBI Platform and Directed To any Licensed Target, that are conceived, made, reduced to practice or developed by Respondents or any of their Affiliates after the Effective Date.

(x) “IND” means (a) an Investigational New Drug Application as defined in the Federal Food, Drug, & Cosmetic Act (“FD&C Act”) and applicable regulations promulgated thereunder by the FDA, and (b) the equivalent application to the applicable Regulatory Agency in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

(y) “Indication” means a class of human disease or condition for which a separate marketing authorization application (including any extensions or supplements) is required to be filed with a Regulatory Agency.

(z) “Intellectual Property Rights” means any and all (A) patents, divisionals, applications, utility models, industrial rights and similar intellectual property rights registered or applied for in the United States and all other countries throughout the world (including all reissues, divisions, continuations, continuations-in-part, renewals, extensions and reexaminations thereof) (collectively, “Patent Rights”); (B) rights in trademarks, service marks, trade dress, logos, domain names, rights of publicity, trade names and corporate names (whether or not registered) in the United States and all other countries throughout the world, including all registrations and applications for registration of the foregoing and all goodwill related thereto; (C) copyrights (whether or not registered) and rights in works of authorship, databases and mask works, and registrations and applications for registration thereof in the United States and all other countries throughout the world, including all renewals, extensions, reversions or restorations associated with such copyrights, now or hereafter provided by law, regardless of the medium of fixation or means of expression; (D) right in inventions, practices, methods, protocols, formulas, know-how, know-how related to manufacturing, testing, characterization and/or similar processes, specifications, formulae, software, algorithms, CMC information, formulations, expertise, test data, stability data, other study data and procedures, trade secrets, processes, assays, techniques and results of experimentation and testing, and other scientific, technical or regulatory information

(including raw data) in the United States and all other countries throughout the world (collectively, “Know-How”); (E) other intellectual property or proprietary rights in the United States and all other countries throughout the world, including all neighboring rights and sui generis rights; (F) rights to apply for, file, register establish, maintain, extend or renew any of the foregoing; (G) rights to enforce and protect any of the foregoing, including the right to bring legal actions for past, present and future infringement, misappropriation or other violations of any of the foregoing; and (H) rights to transfer and grant licenses and other rights with respect to any of the foregoing.

(aa) “Knowledge” means actual knowledge of [*****], after performing due inquiry with respect to the applicable facts and information.

(bb) “Licensed Field” means both the Exclusive Licensed Field and the Non-Exclusive Licensed Field.

(cc) “Licensed Target” means the biological target and/or receptors of each of (a) PDL-1, (b) IL-7, (c) IL-12, (d) IL-18, (e) IL-21 and (f) such additional biological target selected pursuant to Paragraph 5(b).

(dd) “Licensed Products” means (a) TGFb Products, and (b) Non-TGFb Products; *provided that*, the foregoing “(b)” expressly excludes any product

that comprises or is Directed To, as applicable, subject matter that is subject to ImmunityBio's exclusive rights pursuant to Paragraph 5.

(ee) "Non-Exclusive Licensed Field" means neoadjuvant ovarian cancer Indications solely to the extent (i) used in combination with standard of care chemotherapy and (ii) limited to the treatment plan and the indication (if any) as submitted to the FDA by HCW as of the Effective Date.

(ff) "Non-TGFb Product" means any pharmaceutical product in any form that does not (i) contain a TGFb Molecule or (ii) otherwise relate to human transforming growth factor receptors or TGFb traps.

(gg) "Oncology Field" means all uses for oncology diseases, disorders or conditions in humans or animals, including prophylactic or therapeutic treatment, delay or prevention of any oncology diseases, disorders or conditions in humans and animals.

(hh) "Person" means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, but not including a government or political subdivision or any agency or instrumentality of such government or political subdivision.

(ii)"Regulatory Agency" means the FDA and any other governmental authority with responsibility for the approval of the marketing and

sale of pharmaceuticals or biologics or other regulation of pharmaceuticals or biologics.

(jj)“Regulatory Approval” means all approvals (including, without limitation, where applicable, Drug Approval Applications, pricing and reimbursement approval, labeling approval and schedule classifications), licenses, registrations, certificates, permits or authorizations of any Regulatory Agency necessary for the manufacture, use, storage, import, export, transport, offer for sale, or sale of any product or investigational agent, together with all amendments, supplements and updates thereto and all benefits arising therefrom, including any orphan drug exclusivities or other non-patent exclusivities.

(kk) “ROFR Information Package” means (a) the following information Controlled by any Respondent at the time a ROFR Information Package is delivered that summarizes material data relating to the Additional Molecule including (i) structure, (ii) characterization, (iii) data and information supporting the promotion and activation of immune cells, (iv) clinical readouts, (v) pre-IND and IND enabling studies conducted or ongoing, (vi) the competitive advantages of using such fusion proteins for products, (vii) any other information provided to any prospective Third Party licensee, (b) physical samples of such fusion proteins of sufficient quality and quantity to permit ImmunityBio to conduct due diligence

studies thereof, and (c) as applicable, the terms of any proposed Third Party license for any Additional Molecule (excluding the identity of the applicable Third Party).

(ll) [*****].

(mm) “T Cells” means a T-lymphocyte.

(nn) “TGFb Assigned Patents” means the Group A Patents and Group B Patents.

(oo) “TGFb Know-How” means all Know-How Controlled by the Respondents or any of their Affiliates as of the Effective Date or at any time thereafter that is necessary or reasonably useful for the Exploitation of the TGFb Molecules or any TGFb Products.

(pp) “TGFb Molecules” means any molecules Controlled by any Respondent as of the Effective Date or thereafter that were generated through the use of the TOBI Platform related to the human transforming growth factor receptor and TGFb traps, including, without limitation, HCW9218, HCW9219, HCW9209 and any derivatives thereof or therefrom.

(qq) “TGFb Product” means any pharmaceutical product in any form that contains a TGFb Molecule.

(rr) “Third Party” means any Person other than the Claimants, Respondents, or its or their respective Affiliates.

(ss) “TOBI Platform” means HCW’s TOBI™ immunotherapeutic drug design and discovery platform and any modifications, improvements and thereto.

(tt) “Transferred Assets” means (i) the Transferred Intellectual Property Rights, (ii) Transferred Regulatory Materials, (iii) Transferred Invention Records and Prosecution Files, (iv) Transferred Inventory and (v) Transferred Contracts.

(uu) “Transferred Contracts” means the contracts set forth on **Schedule 3**.

(vv) “Transferred Intellectual Property Rights” means (i) the TGFb Assigned Patents, (ii) the TGFb Know-How, and (iii) other than the Group C Patents, all other Intellectual Property Rights (A) as of the Effective Date, necessary or reasonably useful for, and (B) any time thereafter, necessary for or otherwise specific to, the Exploitation of the TGFb Molecules or any TGFb Products Controlled by Respondents or any of their Affiliates (such Patent Rights in (iii), the “HCW Additional Assigned Patents”). For clarity, all rights, title, and interest in and to compositions of matter, all formulations, all methods of treatment, and all methods of manufacture necessary for or reasonably useful for ImmunityBio’s Exploitation of the TGFb Molecules or any TGFb Products that exist as of the Effective Date are included in the Transferred Intellectual Property Rights, and all

formulations, all methods of treatment, and all methods of manufacture necessary for or otherwise specific to ImmunityBio's Exploitation of the TGFb Molecules or any TGFb Products that exist after the Effective Date are included in the Transferred Intellectual Property Rights.

(ww) "Transferred Invention Records and Prosecution Files" means (i) all records, books, documents and files pertaining to and/or demonstrating the inventorship of any Transferred Intellectual Property Rights and (ii) any other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Transferred Intellectual Property Rights.

(xx) "Transferred Inventory" means the inventory of TGFb Molecules and any other biological materials necessary or reasonably useful to Develop the TGFb Molecules, to the extent provided for in **Schedule 2(a)(iii)**.

(yy) "Transferred Regulatory Materials" means all U.S. and foreign regulatory applications, submissions and approvals (including all INDs and Drug Approval Applications and foreign counterparts thereof), and all Regulatory Approvals for TGFb Molecules, and all correspondence with the FDA and other Regulatory Agencies relating to the TGFb Molecules or any of the foregoing regulatory applications, submission and approvals, that, in each case, are in the possession of or Controlled by, or held by Respondents or any of their Affiliates as

of the Effective Date, whether generated, filed or held by or for Respondents or any of their Affiliates or licensees.

(zz) "Treg Products" means any pharmaceutical or biological product that contains or comprises Tregs that have been engineered, modified, or otherwise manipulated ex vivo, as an Active Ingredient, and the primary mechanism of action of such product is through the activities of such Tregs.

(aaa) "Tregs" means regulatory T Cells that are a subpopulation of T Cells which negatively regulate the immune system, maintain tolerance to self-antigens, suppress immune system in cancers, abrogate autoimmune disease or alleviate inflammation.

(bbb) "Wugen" means Wugen, Inc., a Delaware corporation.

(ccc) "Wugen Agreement" means the Exclusive License Agreement entered into as of December 24, 2020 by and between Wugen and HCW, in the form as attached hereto as **Exhibit A**.

2. **All TGFb Molecules.**

(a) Assignment. Respondents hereby assign to ImmunityBio their entire right, title and interest in and to all Transferred Assets effective as of the Effective Date. In furtherance of the foregoing:

(i) Assurances. Respondents agree to execute the Patent Assignment as set forth on **Exhibit B** hereto, as well as the Power of Attorney as set

forth on **Exhibit C** hereto, each as of the Effective Date, and further agree going forward to cooperate with and assist ImmunityBio, and perform all acts deemed necessary or desirable by ImmunityBio, to apply for, obtain, establish, perfect, maintain, evidence, enforce or otherwise protect any of the full benefits, enjoyment, right, title and interest throughout the world in the TGFb Assigned Patents and TGFb Molecules. Such acts may include, but are not limited to, execution of assignments of title and other documents and assistance or cooperation in legal proceedings. Should ImmunityBio be unable to secure Respondents' signature on any such document, in connection with and effective by the Power of Attorney attached hereto as **Exhibit C**, Respondents hereby irrevocably designate and appoint ImmunityBio and its duly authorized representatives as Respondents' agents and attorneys-in-fact, with full power of substitution and delegation, to undertake such acts in Respondents' name as if executed and delivered by Respondents (which appointment is coupled with an interest), and Respondents waive and quitclaim to ImmunityBio any and all claims of any nature whatsoever that they may have or may later have for infringement of any Transferred Intellectual Property Rights;

(ii) Unassigned Assets. In the event that any Party becomes aware of any Transferred Assets (a) that come into existence after the Effective Date and/or (b) was otherwise not assigned in accordance with Paragraph 2, including due to error or because such assignment would require an authorization, approval,

consent or waiver from a Third Party, then such Party will notify the other Party and Respondents will take all actions necessary to effect the assignment of such unassigned Transferred Assets to ImmunityBio, including executing any additional legal instruments reflecting assignment as ImmunityBio deems necessary or useful and/or obtaining any required authorization, approval, consent or waiver from an applicable Third Party.

(iii) Technology Transfer. Within [*****], HCW shall (a) provide ImmunityBio with complete and accurate copies of the TGFb Know-How and all other Transferred Assets as provided for in **Schedule 2(a)(iii)** and (b) deliver to ImmunityBio the Transferred Inventory. HCW shall preserve the TGFb Know-How in the same state as immediately prior to the Effective Date until such TGFb Know-How is transferred in accordance with this Paragraph 2(a)(iii). ImmunityBio will be responsible for all reasonable, necessary and documented transportation costs for the shipment of any materials to ImmunityBio required under **Schedule 2(a)(iii)**. Within [*****] of any assignment of Transferred Assets under Paragraph 2(a)(ii), Respondents shall provide and transfer copies of (if applicable) such Transferred Assets to ImmunityBio, and Respondents or any of their Affiliates shall provide reasonable technical assistance with respect to any such additional Transferred Assets to the extent necessary to permit ImmunityBio's Exploitation thereof. HCW grants to

ImmunityBio a right of reference to any regulatory documentation, submissions or approvals with any Regulatory Agency, including in connection with the Transferred Regulatory Materials, submitted in HCW's or its Affiliate's name (or in the name of any of their respective designees). ImmunityBio grants to HCW a right of reference to the Transferred Regulatory Materials solely in connection with HCW's Exploitation of HCW9218 in the Licensed Field.

(iv) Respondents' Non-Compete. On the Effective Date and thereafter, Respondents shall not, directly or indirectly, generate any derivatives of TGFb Molecules for use in the Oncology Field other than the Non-Exclusive Licensed Field.

(b) Retained Liabilities; Indemnification. For the avoidance of doubt, the transfer provided in Paragraph 2(a) above is a transfer of assets only and the Settling Parties acknowledge and agree that ImmunityBio is not assuming any liabilities of any Respondents or any of their Affiliates arising, accruing or existing as of and prior to the Effective Date, which such liabilities are expressly retained by Respondent ("HCW Retained Liabilities"). For avoidance of doubt, HCW Retained Liabilities includes, without limitation, third party claims arising from infringing activity caused by Exploitation of the Transferred Intellectual Property Rights and for liabilities, including amounts accrued and/or owed, arising out of any Transferred Contract, in all cases prior to the Effective Date. Respondents shall defend,

indemnify, and hold harmless ImmunityBio and its Affiliates and their respective officers, directors, employees, agents, successors and assigns (the “ImmunityBio Indemnitees”) from and against any and all losses, damages, liabilities, actually incurred expenses and costs, including reasonable legal expense and attorneys’ fees (“Losses”) to which any ImmunityBio Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (“Third Party Claim”) arising out of, based on, or resulting from any HCW Retained Liabilities.

(c) License to HCW. Subject to the terms and conditions of this Agreement, including the contingency referenced in this Paragraph 2(c) below, ImmunityBio hereby grants HCW (i) a worldwide, perpetual (subject to this Paragraph 2(c)), fully-paid up, royalty-free, exclusive license, with the right to sublicense, under the TGFb Assigned Patents, the HCW Additional Assigned Patents and the TGFb Know-How, to Exploit Licensed Products, as applicable, in the Exclusive Licensed Field and (ii) a worldwide, perpetual (subject to this Paragraph 2(c)), fully-paid up, royalty-free, non-exclusive license, with the right to sublicense, under the TGFb Assigned Patents, the HCW Additional Assigned Patents and the TGFb Know-How, to Exploit Licensed Products in the Non-Exclusive Licensed Field. HCW hereby grants ImmunityBio a right of first refusal to regain exclusive rights through termination of the license rights granted to HCW pursuant to this Paragraph 2(c) to Exploit Licensed Products for use in the Non-

Exclusive Licensed Field, following the procedures as set forth in Paragraph 6 hereof, *mutatis mutandis*. HCW agrees to provide full access to all safety and clinical data generated in connection with Licensed Products, whether for the Exclusive or Non-Exclusive Licensed Field or otherwise, to ImmunityBio. Notwithstanding the foregoing, in the event that HCW does not initiate (i.e., dose a first patient) a clinical trial of a TGFb Molecule for use in the Non-Exclusive Licensed Field prior to December 31, 2024, then the applicable license granted to HCW as described in this Paragraph 2(c)(ii) shall automatically terminate effective as of such date.

(d) Prosecution and Maintenance.

(i) Rights. For the avoidance of doubt, ImmunityBio shall control and have the first right, but not the obligation, to prepare, file, prosecute, and maintain the TGFb Assigned Patents worldwide. Further, ImmunityBio shall have the first right, but not the obligation, to conduct any opposition, re-issuance, post-grant review, *inter-partes* review, reexamination request, nullity action, interference, or other similar post-grant proceedings and any appeals therefrom relating to the TGFb Assigned Patents worldwide. Notwithstanding the foregoing, and solely with respect to claims contained in a TGFb Assigned Patent that specifically cover the Exploitation of a Licensed Product in the Exclusive Licensed Field (an "Exclusive Licensed Field-Specific Claim"), ImmunityBio shall file, at HCW's expense, any

additional related applications HCW deems reasonably necessary to further protect a Licensed Product in the Exclusive Licensed Field, *provided that*, ImmunityBio may elect not to file such related application(s) to the extent ImmunityBio in good faith believes such application may have any adverse impact on any TGFb Assigned Patents, HCW Additional Assigned Patents or ImmunityBio TGFb Products. ImmunityBio shall provide HCW with a copy of any draft of a material and substantive filing directed to an Exclusive Licensed Field-Specific Claim reasonably in advance of ImmunityBio's filing of such draft to permit HCW, using counsel of HCW's choosing, an opportunity to review and provide reasonable comments and/or instructions thereto within [*****] of HCW's receipt of the applicable draft (or a shorter period reasonably designated by ImmunityBio if [*****] is not practicable given the filing deadline). ImmunityBio will incorporate in good faith all reasonable comments and effect all reasonable instructions related directly to such Exclusive Licensed Field-Specific Claim thereto provided by HCW during the applicable comment period and in connection with the filing thereof; *provided that*, ImmunityBio may elect not to incorporate such reasonable comments to the extent ImmunityBio believes such reasonable comments may have any adverse impact on any TGFb Assigned Patents or ImmunityBio TGFb Products. Notwithstanding anything to the contrary herein, solely for purposes of this Paragraph 2(d), Paragraph 2(e)

and Paragraph 2(f), the HCW Additional Assigned Patents shall be treated as TGFb Assigned Patents, *mutatis mutandis*.

(ii) Costs. HCW and ImmunityBio shall [*****] third party expenses (including reasonable attorneys' fees) incurred in connection with the prosecution or maintenance activities that pertain to Patent Rights comprised of an Exclusive Licensed Field-Specific Claim and a claim that is not an Exclusive Licensed Field-Specific Claim. With respect to all third party expenses (including reasonable attorneys' fees) incurred or to be incurred by ImmunityBio in connection with any prosecution or maintenance activities that pertain solely to an Exclusive Licensed Field-Specific Claim (a) HCW shall reimburse ImmunityBio for all such expenses, and (b) without limiting the foregoing, HCW shall, within HCW's [*****] (or shorter, as applicable) review and comment period, advance to ImmunityBio (or its designee) all such expenses. To the extent HCW does not advance such expenses, ImmunityBio shall have no obligation to take any action with respect to such Exclusive Licensed Field-Specific Claim.

(iii) Step-In Right. ImmunityBio may cease prosecution and/or maintenance of any Exclusive Licensed Field-Specific Claim on a country-by-country basis by providing HCW written notice reasonably in advance (but at least [*****] before the applicable deadline with a relevant patent authority). If ImmunityBio elects to cease prosecution or maintenance of the relevant Exclusive

Licensed Field-Specific Claim in a country, HCW, shall have the right, but not the obligation, at its sole discretion and cost, to continue prosecution or maintenance of such Exclusive Licensed Field-Specific Claim and in such country with counsel of its choosing.

(e) Enforcement.

(i) Rights. If either Party becomes aware of any existing or threatened infringement of any TGFb Assigned Patent ("Infringement"), it shall promptly notify the other Party in writing to that effect. Respondents shall share with ImmunityBio all information available to it regarding such alleged Infringement, pursuant to a mutually agreeable "common interest agreement" executed by the Parties under which the Parties agree to their shared, mutual interest in the outcome of any suit or other action to enforce the TGFb Assigned Patent against such Infringement. ImmunityBio shall have (a) with respect to any Infringement of the TGFb Assigned Patents, the sole right; *provided that*, such Infringement is not subject to clause (b), and (b) with respect to any Infringement that is solely of an Exclusive Licensed Field-Specific Claim, the first right, and in each case of clause (a) and (b), but not the obligation, to bring an appropriate suit or other action against any Person engaged in the Infringement of any TGFb Assigned Patent or Exclusive Licensed Field-Specific Claim, as applicable, [*****]. If the applicable Infringement is solely with respect to an

Exclusive Licensed Field-Specific Claim and ImmunityBio notifies HCW in writing that it does not intend to commence a suit or other action to enforce the applicable Exclusive Licensed Field-Specific Claim against such Infringement or to take other action to secure the abatement of such Infringement, or fails to take any such action after a period of [*****] following either Party's receipt of the notice of Infringement pursuant to this Paragraph 2(e)(i) then, HCW shall have the right, but not the obligation, to commence such a suit or take such action, at [*****] and using counsel of its choosing.

(ii) Recoveries. Any amounts recovered in connection with an Infringement suit or action under Paragraph 2(e)(i) shall first be used to reimburse ImmunityBio and HCW for their costs and expenses incurred in connection with such Infringement suit or action and all remaining amounts shall be divided as follows: (a) with respect to an Infringement suit or action that relates to only claims that are not Exclusive Licensed Field-Specific Claims, [*****]; (b) with respect to an Infringement suit or action (1) that relates to both claims that are not Exclusive Licensed Field-Specific Claims and Exclusive Licensed Field-Specific Claims or (2) that is controlled by ImmunityBio and relates to only Exclusive Licensed Field-Specific Claims, [*****]; and (c) with respect to an Infringement suit or action that is controlled by HCW and relates to only Exclusive Licensed Field-

Specific Claims, [*****].

(f) Cooperation. Each Party shall cooperate with the Party controlling the prosecution and/or enforcement of any TGFb Assigned Patent, at the controlling Party's request and, subject to Paragraph 2(d)(ii) expense. To the extent that HCW exercises or intends to exercise its rights under Paragraphs 2(d) or 2(e), (i) [*****] incurred in connection therewith and (ii) notwithstanding Paragraphs 2(d) and 2(e), if ImmunityBio reasonably believes that HCW's initiation or continued prosecution, maintenance or enforcement, as applicable, of any such Exclusive Licensed Field-Specific Claim may have an adverse impact on any TGFb Assigned Patents or ImmunityBio TGFb Products, then HCW shall not have the right to continue the prosecution, maintenance or enforcement, as applicable, of such Exclusive Licensed Field-Specific Claim.

(g) License to ImmunityBio. Respondents hereby grant ImmunityBio (i) a worldwide, perpetual, irrevocable, fully-paid up, royalty-free, non-exclusive license, with the right to grant and authorize sublicenses through multiple tiers, under (A) the Group C Patents, and (B) any other Intellectual Property Rights Controlled by Respondents or any of their Affiliates after the Effective Date and reasonably useful for the Exploitation of TGFb Molecules or TGFb Products, in

each of (A) and (B), for all uses in the Oncology Field; and (ii) a worldwide, perpetual, irrevocable, fully-paid up, royalty-free, exclusive license (subject only to ImmunityBio's license to HCW under Paragraph 2(c)(ii) to Exploit Licensed Products in the Non-Exclusive Licensed Field), with the right to grant and authorize sublicenses through multiple tiers, subject to and in accordance with Paragraph 2(a)(ii), any other Transferred Intellectual Property Rights that are unable to be assigned and until such time that such Transferred Intellectual Property Rights, as applicable, are assigned, for all uses in the Oncology Field.

(h) Publicity. HCW agrees to update its corporate website pipeline to be consistent with this arrangement limiting HCW9218 to the Licensed Field.

3. **NK Cell Memory Like Activation Technology.**

(a) Subject to the terms and conditions of this Agreement, Respondents hereby grant ImmunityBio a worldwide, perpetual, irrevocable, fully-paid up, royalty-free, non-exclusive license, with the right to sublicense, under any Intellectual Property Rights Controlled by the Respondents or any of their Affiliates as of the Effective Date and thereafter, to Exploit HCW9201 (IL12/IL15/IL18) solely as a subcutaneous injection (in vivo). For clarity, the foregoing license grant excludes any rights exclusively granted to Wugen under the Wugen Agreement as of the Effective Date.

(b) Within [*****] (or such longer period as requested by ImmunityBio), HCW shall perform a manufacturing technology transfer to ImmunityBio or its designee sufficient to permit ImmunityBio or its designee to manufacture HCW9201, which shall comprise a transfer of complete and accurate copies of all Know-How Controlled by the Respondents or any of their Affiliates as of the Effective Date that is necessary or reasonably useful in exercising ImmunityBio's rights under the license grant set forth in Paragraph 3(a) including, without limitation, transfer of the materials and documentation as set forth in **Schedule 2(a)(iii)**, as well as any inventory and materials pertaining to HCW9201 (replacing HCW9218 and HCW 9101 with HCW9201, as appropriate) as set forth in **Schedule 2(a)(iii)**.

(c) Respondents shall defend, indemnify, and hold harmless ImmunityBio Indemnitees from and against any and all Losses to which any ImmunityBio Indemnitee may become subject as a result of any Third Party Claim arising out of, based on, or resulting from ImmunityBio's exercise of the licenses granted under Paragraph 3(a), including the Exploitation of HCW9201, solely to the extent such Third Party Claim (i) alleges infringement or misappropriation of such Third Party's Intellectual Property Rights as a direct result of ImmunityBio's exercise of the licenses granted under Paragraph 3(a), (ii) arises in connection with the rights granted to Wugen under the Wugen Agreement or any amendments or

modifications thereto, or (iii) arises in connection with the gross negligence or willful misconduct of Respondents or any of their Affiliates in connection with the performance of Respondents' obligations under Paragraph 3(b).

4. **All Affinity Purification and Column Technology.**

(a) Subject to the terms and conditions of this Agreement, Respondents hereby grant ImmunityBio a worldwide, perpetual, irrevocable, fully-paid up, royalty-free, non-exclusive license, with the right to sublicense, under any Intellectual Property Rights Controlled by the Respondents or any of their Affiliates as of the Effective Date and thereafter, to Exploit (i) the HCW9101 master cell bank [*****] to manufacture and purify cGMP HCW9218 and (ii) master and research cell banks for the TGFb Molecules for manufacturing and purification of tissue factor based fusion proteins. Within [*****], HCW shall provide ImmunityBio with complete and accurate copies of all Know-How Controlled by the Respondents or any of their Affiliates as of the Effective Date or thereafter and necessary or reasonably useful in exercising ImmunityBio's rights under the license grant set forth in this Paragraph 4(a) including, without limitation, transfer the materials and documentation as set forth in **Schedule 2(a)(iii)**, as well as any inventory and materials as set forth in **Schedule 2(a)(iii)**. For clarity, such technology transfer shall include, without limitation, Know-How

sufficient for [*****] and shall be subject to the same ongoing obligations and procedure as set forth in Paragraph 2(a)(ii), *mutatis mutandis*, including with respect to any applicable Improvements and ongoing support.

(b) Respondents shall, as of the Effective Date, execute and deliver to each of ImmunityBio and EirGenix a signed letter in the form attached as **Exhibit D**. Further, Respondents hereby consent and agree to the assignment as set forth under the terms of this Agreement of the Transferred Contracts to ImmunityBio, subject only to the consent of EirGenix (or other third party thereto), as required. Further, nothing in this Agreement shall be interpreted as limiting or restricting ImmunityBio from entering into a direct contractual relationship with HCW's Third Party contract manufacturing organization(s), including EirGenix, and Respondents represent that Respondents have not taken, and will not take, any action (or inaction) to interfere with or prevent ImmunityBio's exercise of ImmunityBio's rights with respect to EirGenix. Nothing in this Agreement shall be construed as an attempt or agreement to assign or transfer any Transferred Contract to ImmunityBio which by its terms is not assignable or transferable without a consent or is cancelable by a Third Party in the event of an assignment or transfer (a "Non-Assignable Contract"), unless and until such consent shall have been obtained. Respondents and ImmunityBio shall obtain as expeditiously as possible any consent that may be

required for the assignment or transfer of the Non-Assignable Contract to ImmunityBio, and Respondents shall take all such actions as may be necessary to effect the assignment and transfer of the Non-Assignable Contract. Unless and until any such consent that may be required is obtained, Respondents shall establish an arrangement reasonably satisfactory to ImmunityBio under which ImmunityBio would obtain the rights, claims and benefits under such Non-Assignable Contract (including by means of any subcontracting, sublicensing or subleasing arrangement) or under which Respondents would enforce for the benefit of ImmunityBio, any and all rights, claims and benefits of Respondents against a third party thereto.

(c) For the avoidance of doubt, HCW shall control and have the first right, but not the obligation, to prepare, file, prosecute, and maintain the patents licensed to ImmunityBio pursuant to Paragraph 4(a) (other than the TGFb Assigned Patents which are subject to the assignment under Paragraph 2) (the "9101 Patents") worldwide. Further, HCW shall have the first right, but not the obligation, to conduct any opposition, re-issuance, post-grant review, inter-partes review, reexamination request, nullity action, interference, or other similar post-grant proceedings and any appeals therefrom relating to the 9101 Patents. HCW shall provide ImmunityBio with a copy of the draft prepared for the filing of any claim contained in a 9101 Patent (a "9101 Specific Claim") before the filing of such 9101 Specific Claim and will consider in good faith comments thereto provided by

ImmunityBio in connection with the filing thereof. HCW shall provide ImmunityBio with regular updates on the prosecution of the 9101 Specific Claims. HCW may cease prosecution and/or maintenance of any 9101 Specific Claim on a country-by-country basis by providing ImmunityBio written notice reasonably in advance (but at least [*****] before the applicable deadline with a relevant patent authority). If HCW elects to cease prosecution or maintenance of the relevant 9101 Specific Claim in a country, ImmunityBio shall have the right, but not the obligation, at its sole discretion and cost, to continue prosecution or maintenance of such 9101 Specific Claim and in such country.

5. **ImmunityBio's Choice of Six (6) Licensed Targets and Associated TOBI Platform Products.**

(a) Respondents hereby grant to ImmunityBio, with respect to each Licensed Target, a worldwide, perpetual, irrevocable, fully-paid up, royalty-free, exclusive (even as to Respondents) license, with the right to sublicense through multiple tiers, under all Intellectual Property Rights Controlled by Respondents or any of their Affiliates as of the Effective Date and any Improvements thereto, to Exploit Licensed Targets and any products (other than the fusion proteins referred to as HCW9206 and HCW9302), including any fusion proteins, molecules and/or antibodies therein, created by Respondents prior to the Effective Date or by either Party thereafter utilizing the TOBI Platform Directed To a Licensed Target ("TOBI

Platform Products"), solely in the Oncology Field; provided that, the foregoing license grant excludes the right to Exploit any Cellular Therapy Products ex vivo to the extent exclusively licensed to Wugen pursuant to the Wugen Agreement as of the Effective Date. For clarity, from and after the Effective Date, Respondents shall not, and shall cause its Affiliates, acquirors and/or sublicensees not to, institute or prosecute, any claim demand, action or other proceeding for damages, costs, expenses or compensation, or for an enjoinment, injunction or any other equitable remedy, against ImmunityBio or any of its Affiliates, acquirors and/or sublicensees alleging that the Exploitation of Licensed Targets or TOBI Platform Products in any way infringes any Intellectual Property Rights owned or Controlled by Respondents or any of its Affiliates, acquirors or sublicensees, including, without limitation, those covering HCW9206 or HCW9302.

(b) ImmunityBio shall choose one (1) additional Licensed Target at its sole discretion within the next six (6) months following the Effective Date ("Target Evaluation Period").

(c) In connection with ImmunityBio's right to choose one (1) additional Licensed Target at its sole discretion during the Target Evaluation Period, with respect to any biological target, Respondents shall provide ImmunityBio (i) all material data, results, presentations and other information related to such biological target and any fusion proteins, molecules and/or antibodies Directed To such target

that is necessary or reasonably useful for ImmunityBio to evaluate whether to select such target to be a Licensed Target and (ii) at ImmunityBio's reasonable request, direct access to personnel of Respondents for the purpose of evaluating and discussing the information described in clause (i). In the event that ImmunityBio selects a new biological target to be a Licensed Target pursuant to this Paragraph 5, it shall provide written notice of such selection to the Respondents. Upon expiration of the Target Evaluation Period, ImmunityBio shall have no further right under this Paragraph 5 to select biological targets not already selected to be a Licensed Target.

(d) The Licensed Targets (i) shall be exclusive to ImmunityBio (even as to Respondents) as to any fusion protein, molecule and/or antibody created utilizing the TOBI Platform in the Oncology Field, such that Respondents cannot Develop, manufacture Commercialize, or Exploit, or license, authorize, appoint or otherwise enable any other Third Party to Develop, manufacture, Commercialize or Exploit, any fusion protein, molecule and/or antibody created utilizing the TOBI Platform Directed To such Licensed Target or that is a derivative of a pre-existing fusion protein, molecule and/or antibody created utilizing the TOBI Platform Directed To such Licensed Target, in either case, in the Oncology Field (but excluding the fusion proteins referred to as HCW9206 and HCW9302) and (ii) the sequence of such selected Licensed Target shall be the sole confidential information

of ImmunityBio and subject to terms and conditions of Paragraph 19 of this Settlement.

(e) ImmunityBio's right to file, prosecute, maintain, and enforce any licensed Intellectual Property Rights granted under the license set forth in Paragraph 5(a) shall be as set forth in Paragraphs 2(d) through (f) (inclusive), *mutatis mutandis*.

6. **Right of First Refusal for ImmunityBio.**

(a) Respondents hereby grant to ImmunityBio an exclusive option and right of first refusal to obtain an exclusive license to any Additional Molecule in the Oncology Field (the "ROFR"). If Respondents or any of their Affiliates desires to enter into any transaction with a Third Party for the license, transfer, or other disposition of any Additional Molecule for use in the Oncology Field (each, a "ROFR Transaction"), HCW will provide prompt written notice to ImmunityBio ("ROFR Notice"). Such ROFR Notice provided by HCW to ImmunityBio shall be accompanied by a ROFR Information Package and a Non-Disclosure Agreement to govern the treatment of the ROFR Information Package. ImmunityBio may exercise its ROFR by providing HCW with written notice thereof ("Exercise Notice") by the date that is [*****] following ImmunityBio's receipt of a ROFR Notice by HCW. The Exercise Notice shall identify the Additional Molecule with respect to which ImmunityBio has an interest in

exercising its ROFR. Following HCW's receipt of such Exercise Notice, the Parties will enter into good faith negotiations for a license for a period not to exceed [*****]. The financial terms of any such license shall reasonably reflect the scope and content of the license grant, including its exclusivity, the Additional Molecule, the licensed Indication and the licensed territory. Notwithstanding the foregoing, and even if such aggregate [*****] period has expired, neither Respondents nor any of their Affiliates shall grant licenses or other rights to any Additional Molecule to any Third Party without first providing ImmunityBio with notice that a Third Party license is sought, including disclosure to ImmunityBio of all material terms of such Third Party's offer, and giving ImmunityBio the opportunity to match such Third Party offer and exercise its ROFR with respect to such Additional Molecule. If ImmunityBio does not exercise its ROFR as provided in this Paragraph 6, or if the Parties do not complete negotiations for a license related to any Additional Molecule for which such Third Party license is sought within the time periods set forth in this Paragraph 6, then Respondents will be free to grant such Third Party license to the applicable Third Party for such Additional Molecule provided that such license shall be on terms no more favorable to such Third Party than the license terms last offered by ImmunityBio in writing; provided further that, if Respondents or any of their Affiliates desire to enter into a new ROFR Transaction, including, for clarity, for the same Additional Molecule, the procedure

set forth in this Paragraph 6 shall apply to each such new ROFR Transaction. For the avoidance of doubt, Respondents agree that they will not, directly or indirectly, Develop, make, have made, use or Commercialize any Additional Molecule for use in the Oncology Field, without first complying with the procedures described in this Paragraph 6.

7. **Other Provisions Regarding the License Grants.**

(a) Except as explicitly set forth in this Settlement, none of the Respondents nor Claimants shall be deemed by estoppel or implication to have granted any other party (including Claimants and Respondents, respectively) any license or other right to any intellectual property of such Respondent.

(b) No later than [*****], the Parties shall define and finalize the actions that the Parties shall employ with respect to Licensed Products in any Licensed Field to protect patients and promote their well-being in a written pharmacovigilance agreement (the “Pharmacovigilance Agreement”) for the Development and Commercialization of the Licensed Products in any Licensed Field globally. The Pharmacovigilance Agreement shall include mutually acceptable guidelines and procedures for the receipt, investigation, recording, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of the Licensed Products in any Licensed Field, and other

routine pharmacovigilance reporting requirements. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable laws. Furthermore, such agreed procedure shall be consistent with relevant ICH guidelines, except where said guidelines may conflict with existing local regulatory reporting requirements, in which case the local reporting requirements shall prevail. As between the Parties, ImmunityBio shall be responsible for preparing all adverse event reports and responses to safety issues and requests of Regulatory Agencies relating to Licensed Products in any Licensed Field. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and (sub)licensees to comply with such obligations.

8. **Proceedings Against Claimants and ImmunityBio.**

(a) [*****].

9. **Forensic and Other Remediation of Certain Information and Data Repositories.**

(a) Within [*****], each Respondent (*i.e.*, HCW and Dr. Wong) and each HCW employee who previously worked for Altor or NantCell and is still employed by or acting as a consultant for HCW shall affirm, by signing a declaration under oath in the form attached to this Agreement as **Exhibit E**, stating that: (1) they do not possess, are not using, and will not use any confidential and/or proprietary information of Claimants ("Claimants' Confidential Materials"), including but not limited to (i) emails (and/or attachments) sent to or from their Altor or NantCell email addresses during their time at Altor or NantCell and (ii) documents stored on Altor's private corporate servers and copies thereof; (2) they have conducted a reasonably diligent search of all Information Sources in their possession, have destroyed any Claimants' Confidential Materials in their possession (other than HCW backups or archives that are not ordinarily accessible and which Dr. Wong agrees not to access and HCW agrees not to permit its employees to access), and have concluded that they no longer possess or have access to any Claimants' Confidential Materials; (3) they understand they have an ongoing obligation to promptly destroy any Claimants' Confidential Materials without using or disclosing such materials, if they later discover any such materials in their possession; and (4) they have not provided and will not provide any Claimants' Confidential Materials to any third party. Each of Respondents and each HCW employee who previously worked for Altor or NantCell and is still employed

by or acting as a consultant for HCW shall return such signed declaration to Claimants within [*****].

(b) For the purposes of this Agreement, “Information Sources” shall include, but not be limited to, (i) HCW file servers, (ii) HCW email systems or email servers, (iii) HCW laptop or desktop computers, (iv) Altor laptops or desktop computers, (v) Altor lab notebooks or physical notebooks used for Altor work while at Altor, (vi) portable storage devices (including but not limited to USB devices) of Respondents or HCW employees who previously worked for Altor or NantCell, (vii) personal emails, files, or text messages of Dr. Wong and other HCW employees who previously worked for Altor or NantCell, and (viii) any backups and archives of the foregoing. A “reasonably diligent search” shall include, but not be limited to, diligent searches to identify all emails containing Altor or NantCell domain names, all documents bearing the logo of or referencing that it is an Altor or NantCell document, all documents describing or relating to Altor’s or NantCell’s research, and all documents previously downloaded from Altor or NantCell company servers.

(c) For the purposes of this Agreement, “Claimants’ Confidential Materials” does not include information that (i) is or becomes generally available to the public other than as a result of disclosure by Respondents in violation of this Paragraph 9, so long as Respondents first obtained the information after they had become generally available to the public, or (ii) becomes available to

Respondents on a non-confidential basis from a source that has the right to disclose such information. For the avoidance of doubt, “Claimants’ Confidential Materials” includes all materials, if any, in Respondents’ or their representatives’ or Affiliates’ possession that were trade secret, confidential, proprietary, and/or internal to Claimants and were obtained as a result of, or in connection with, Dr. Wong’s or other HCW employees’ prior employment with Altor or NantCell.

(d) Within [*****], HCW’s counsel and [*****] shall destroy or oversee the destruction of the following portable storage devices (including any copies, backups, or archives) which constitute Information Sources: (i) [*****], (ii) [*****], (iii) [*****], and (iv) [*****].

(e) Within [*****], HCW’s counsel shall oversee the forensic remediation process referenced in Paragraph 78-79 of the Rebuttal Expert Report [*****], dated April 23, 2024.

(f) Claimants contend that a hard drive with serial number [*****], a hard drive with serial number [*****],

and potential copies of the [*****] may also contain Claimants' confidential information and trade secrets. Respondents agree that if any of these devices are located, they will either be (i) destroyed promptly, or (ii) provided to Respondents' counsel who will promptly notify Claimants' counsel within [*****] of Respondents' discovery of such devices.

(g) Nothing in this Agreement shall limit or affect the Parties' ongoing obligations under employment, confidentiality, and non-disclosure agreements previously executed in connection with Dr. Wong's or other HCW employees' prior employment with Altor or NantCell, to the extent any such ongoing obligations exist.

10. **HCW Retained Rights.**

(a) Subject to the terms and conditions of this Agreement, HCW will retain freedom to develop the TOBI Platform for all indications and uses.

11. **Legal Fees.**

(a) [*****].

All Parties will be responsible for their share of expenses, including expenses of the Arbitrator, invoiced by JAMS. ImmunityBio agrees to release its pending claim against HCW for contribution of funds it has advanced that was filed in the Delaware Court of Chancery, captioned *Altor Bioscience, LLC, et al. v. HCW Biologics, Inc.,* C.A. No. 2024-0310-PAF, and to dismiss that action. Other than as set forth in this Paragraph 11, each Party shall bear its own expenses, costs, and fees in connection with the Action and this Agreement, including any expenses, costs, or fees incurred by its attorneys, experts, advisors, agents, or representatives.

12. **Representations and Warranties of Respondents.** Each Respondent, as to himself, herself, or itself, as applicable, hereby represents and warrants to, and covenants and agrees with, Claimants, as of the date hereof, as follows:

(a) Respondents have the right to grant the rights, transfers and assignments granted herein, without the need for any assignments, releases, consents, approvals, immunities or other rights not yet obtained;

(b) The Transferred Assets are solely and exclusively owned by Respondents or its Affiliates and are free of and not subject to any restrictions or to any mortgages, liens, pledges, security interests, encumbrances or encroachments;

(c) Each of the patents and trademarks included in the Transferred Intellectual Property Rights is valid, enforceable and subsisting and has

not lapsed, expired, been cancelled or become abandoned and all applicable fees have been paid on or before the due date for payment;

(d) **Schedule 1** attached hereto is complete, true and accurate and contains all patents and patent applications Controlled by the Respondents, whether published or unpublished, that are related to the TGFb Molecules or necessary or reasonably useful for the research, Development, Commercialization, use, sale or Exploitation of the TGFb Molecules;

(e) To the Knowledge of the Respondents, except for the Transferred Intellectual Property Rights, no other rights or licenses (including other Intellectual Property Rights) are necessary to use, Develop, manufacture, import Commercialize or Exploit the TGFb Molecules;

(f) To the Knowledge of the Respondents, except for the Transferred Intellectual Property Rights, no other rights or licenses (including other Intellectual Property Rights) are necessary to use, Develop, manufacture, import, Commercialize or Exploit HCW9201 for use as a subcutaneous injection;

(g) The materials, inventory, documentation and other technology transferred to ImmunityBio as set forth in **Schedule 2(a)(iii)**, and pursuant to Paragraphs 2(a)(iii), 3 and 4, contain all that are needed to manufacture the TGFb Molecules and HCW9101 on a level consistent with Respondents and/or its Third Party contract manufacturers, including without limitation EirGenix, as of

the Effective Date, and Respondents are not withholding anything necessary or reasonably useful for the manufacturing of the TGFb Molecules and HCW9101.

(h) The Transferred Contracts set forth on Schedule 3 are all Third Party agreements to which HCW is a Party that are necessary for the use, Development, manufacture, importation, Commercialization of Exploitation of the Transferred Assets. HCW has made available to ImmunityBio prior to the Effective Date a true, complete and correct copy of each Transferred Contract as in effect on the date of this Agreement. HCW is not currently and, to the Knowledge of Respondents, no other party to a Transferred Contract is, in breach of or default of the terms of any Transferred Contract. Each Transferred Contract is a legal, valid and binding obligation of HCW or its Affiliates and is in full force and effect.

(i) The Wugen Agreement attached as **Exhibit A** is a true and complete copy as of the Effective Date.

(j) As of the Effective Date, the Wugen Agreement has not been amended or modified and Wugen has not exercised any of Wugen's option rights thereunder.

13. **Release by Claimants.**

(a) Each of the Claimants and their respective present or former agents, affiliates, successors, assigns, predecessors, parents, subsidiaries, representatives, trustees, executors, heirs, spouses, marital communities, or

transferees, immediate or remote, and any person or entity acting for or on behalf of any of them and each of them (collectively the “Claimant Releasing Parties”), without any other action being required to be taken, do hereby completely, finally, and fully forever release, remise, acquit, compromise, settle, extinguish, relinquish, and forever discharge without limitation, Respondents and their respective predecessors, successors-in-interest, direct and/or indirect parents, direct and/or indirect subsidiaries, affiliates, representatives, agents, trustees, executors, heirs, spouses, marital communities, assigns, or transferees, immediate or remote, and any person or entity acting for or on behalf of any of them and each of them (collectively, the “Respondent Released Parties”) (except for [*****], which are expressly excluded from and shall not constitute Respondent Released Parties) from any and all causes of action, suits, charges, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, appraisal rights, torts, controversies, agreements, promises, variances, trespasses, damages, judgments, executions, claims, and demands whatsoever, whether asserted or unasserted, contingent or remote, known or unknown, and whether arising in law, admiralty, or equity that the Claimant Releasing Parties or any of them had, now have, or that their successors or assigns hereinafter can, shall, or may have, for, upon,

or by reason of any matter, cause, or thing whatsoever that have been or could have been asserted by the Claimants, in any forum, including class, derivative, individual, or other claims, whether state, federal, or foreign, common law, statutory, or regulatory, including, without limitation, claims under the federal securities laws (collectively, the "Claimants' Settled Claims"); provided, however, that the Claimants' Settled Claims shall not include (i) the right of the Claimants to enforce the terms of this Agreement, or (ii) any rights or claims that arise after the Effective Date.

14. **Release by Respondents.**

(a) Respondents and their respective present or former agents, affiliates, successors, assigns, predecessors, parents, subsidiaries, representatives, trustees, executors, heirs, spouses, marital communities, or transferees, immediate or remote, and any person or entity acting for or on behalf of any of them and each of them (collectively the "Respondent Releasing Parties," and together with the Claimant Releasing Parties, the "Releasing Parties"), without any other action being required to be taken, do hereby completely, finally, and fully forever release, remise, acquit, compromise, settle, extinguish, relinquish, and forever discharge without limitation, the Claimants and their respective predecessors, successors-in-interest, parents, subsidiaries, affiliates, representatives, agents, trustees, executors, heirs, spouses, marital communities, assigns, or transferees, immediate or remote, and any

person or entity acting for or on behalf of any of them and each of them (collectively, the “Claimant Released Parties”) from any and all causes of action, suits, charges, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, appraisal rights, torts, controversies, agreements, promises, variances, trespasses, damages, judgments, executions, claims, and demands whatsoever, whether asserted or unasserted, contingent or remote, known or unknown, and whether arising in law, admiralty, or equity that the Respondent Releasing Parties or any of them had, now have, or that their successors or assigns hereinafter can, shall, or may have, for, upon, or by reason of any matter, cause, or thing whatsoever that have been or could have been asserted by Respondents, in any forum, including class, derivative, individual, or other claims, whether state, federal, or foreign, common law, statutory, or regulatory (collectively, the “Respondents’ Settled Claims,” and together with the Claimants’ Settled Claims, the “Settled Claims”); provided, however, that the Respondents’ Settled Claims shall not include (i) the claims referenced in Paragraph 8 of this Settlement, subject to the terms therein, (ii) the right of Respondents to enforce the terms of this Settlement, or (iii) any rights or claims that arise after the Effective Date.

15. **Release of Unknown Claims.** The Parties understand and agree that the releases described herein shall extend to claims that the Releasing Parties do not know or suspect to exist at the time of the release, which if known, might have

affected the Releasing Parties' decisions to enter into the releases. The Releasing Parties shall be deemed to relinquish, to the extent applicable and to the full extent permitted by law, the provisions, rights, and benefits of Section 1542 of the California Civil Code, which states that:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

The Releasing Parties shall be deemed to waive any and all provisions, rights and benefits conferred by any law of any state or territory of the United States, or principle of common law, that is similar, comparable, or equivalent to Section 1542 of the California Civil Code. The Releasing Parties acknowledge that they may discover facts in addition to or different from those that they now know or believe to be true with respect to the subject matter of this Agreement, but that it is their intention to fully, finally, and forever settle and release any and all claims released in Paragraphs 13-14, whether known or unknown, suspected or unsuspected, which now exist or heretofore existed or may hereafter exist and without regard to the subsequent discovery or existence of such additional or different facts. Each Party acknowledges that the foregoing waiver was separately bargained for, is an integral

element of this Agreement, and was relied upon by the other Parties in entering into this Agreement.

16. **Dismissal of Arbitration and Delaware Action.** Upon execution of this Agreement by all Parties, the Parties will inform the Arbitrator in the pending JAMS arbitration (*Altor BioScience, LLC, et al. vs. Hing C. Wong, et al.* – JAMS Ref No. [*****] (the "Arbitration")) that the Arbitration has settled, and ask the Arbitrator to refrain from further work pending dismissal. Claimants and Respondents will cooperate to arrange for prompt dismissal of (i) the Arbitration; and (ii) the pending action in the Delaware Court of Chancery, *Altor Bioscience, LLC v. HCW Biologics, Inc.*, *C.A. No. 2024-0310-PAF*, after Respondents' compliance with Paragraphs 2 through 9 above. To that end, counsel for the Parties shall work together to submit stipulations of dismissal in the Arbitration and the pending action in the Delaware Court of Chancery no earlier than [*****], but as soon as practicable thereafter.

17. **No Assignment.** The Parties represent that they have not assigned or transferred, or purported to assign or transfer, to any person or entity any claim released in this Agreement.

18. **No Admission of Liability.** This Agreement constitutes a compromise of disputed claims. This Agreement shall not be deemed a presumption, a concession, or an admission by any Party of any fault, liability, or wrongdoing as to

any facts, claims, or defenses that have been or might have been alleged or asserted in the Action, and shall not be interpreted, construed, deemed, invoked, offered, received in evidence, or otherwise used by any person in any claim, action, proceeding, or settlement negotiation, except for any litigation or proceeding arising out of or relating to the terms of this Agreement, whether civil, criminal, or administrative, for any purpose other than as provided expressly herein. Notwithstanding the preceding sentence, this Agreement, proof of its execution, and payment of consideration under its terms shall be admissible to prove settlement and release of the claims set forth herein if such shall be necessary. In the event that this Agreement is rendered null and void for any reason, the existence of or the provisions contained in this Agreement shall not be deemed to prejudice in any way the respective positions of the Parties.

19. **Disclosure and Confidentiality.** This Settlement (its existence, and its terms) and all documents, communications, drafts and other materials of any kind relating to their negotiation, the circumstances leading thereto, or the implementation thereof shall be and remain confidential and shall not be disclosed to any other person without the Parties' prior, express, written consent, except as required by applicable law, rule or regulation, or to comply with or enforce the terms of the Settlement itself. There will be no press releases, web site announcements or other public statements by any Party or any of their representatives regarding this

Settlement or any of the matters referenced herein or therein other than as required by law. Notwithstanding the foregoing, each of the Parties may disclose the terms of this Settlement to his, her, or its respective attorneys, accountants, insurers, and/or regulators, and the Parties may disclose the terms as necessary in any required SEC or other regulatory filings or communications.

20. **Entire Agreement; No Reliance.** This Agreement constitutes the entire agreement of the Parties and replaces, cancels, and supersedes any and all prior agreements and understandings between them pertaining to the subject matter hereof. There is no separate agreement, representation, or other inducement between the Parties for the execution of this Agreement. In entering into this Agreement, no Party is relying upon any representation, commitment, warranty, or promise by any other Party unless expressly set forth in this Agreement. The Parties agree this provision is an “anti-reliance” provision under Delaware law precluding claims based on any representation, commitment, warranty, or promise whatsoever not set forth in this Agreement.

21. **Counterparts.** This Agreement may be executed in any number of counterparts, by original or electronically transmitted signature, all of which shall be considered one and the same agreement, and shall become effective when all such counterparts have been signed by each of the Parties and delivered to all of the other Parties.

22. **Mutual Drafting.** The Parties to this Agreement agree that they have thoroughly discussed all aspects of this Agreement with their attorneys, that they have read and fully understand all of the provisions of this Agreement, and that they are voluntarily entering into this Agreement. The Parties further agree that this Agreement has been jointly negotiated and prepared and that no Party shall be deemed to have prepared this Agreement for purposes of construing its terms.

23. **Authorization.** Each of the individuals executing this Agreement hereto on behalf of one or more of the Parties warrants and represents that he or she has been duly authorized and empowered to execute this Agreement on behalf of each such respective Party and to bind each such respective Party to the terms hereof.

24. **Further Actions.** The Parties and their attorneys agree to cooperate fully and to use their best efforts to effectuate expeditiously the terms and conditions of this Agreement, including the execution of all related documents, as soon as practicable. Counsel for the Parties are expressly authorized to enter into such changes, modifications, or amendments of this Agreement as to which they mutually agree as long as such changes are in writing.

25. **No Waiver.** Any failure by any Party to insist upon the strict performance by any other Party of any of the provisions of this Agreement shall not be deemed a waiver of any of the provisions hereof, and such Party, notwithstanding

such failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Agreement to be performed by such other Party.

26. **Choice of Law and Forum.** This Agreement and any and all disputes arising out of or relating in any way to this Agreement, whether in contract, tort, or otherwise, shall be governed by, and construed in accordance with, the laws of the state of Delaware, without regard to conflicts of law principles. Each of the Parties (a) irrevocably submits to the personal jurisdiction of any state or federal court sitting in Wilmington, Delaware, as well as to the jurisdiction of all courts to which an appeal may be taken from such courts, in any suit, action, or proceeding arising out of or relating to this Agreement and/or the Settlement, (b) agrees that all claims in respect of such suit, action, or proceeding shall be brought, heard, and determined exclusively in the Court (provided, however, that in the event that subject matter jurisdiction is unavailable in the Court, then all such claims shall be brought, heard, and determined exclusively in any other state or federal court sitting in Wilmington, Delaware), (c) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from such court, (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, and (e) expressly waives and agrees not to plead or to make any claim that any such action or proceeding is subject (in whole or in part) to a jury trial. Each of the Parties waives any defense of inconvenient forum to the maintenance of any

action or proceeding brought in accordance with this paragraph. Each of the Parties further agrees to waive any bond, surety, or other security that might be required of any other party with respect to any action or proceeding, including an appeal thereof. Each of the Parties further consents and agrees that process in any suit, action, or proceeding may be served on such Party by certified mail, return receipt requested, addressed to such Party or such Party's registered agent in the state of its incorporation or organization, or in any other manner provided by law. Each of the Parties further consents and agrees that process in any suit, action, or proceeding may be served by mailing or emailing such written notice to:

If to Claimants:

[*****]

If to Respondents:

[*****]

27. **Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, executors, administrators, successors, and assigns, and upon any corporation or other entity with which any Party hereto may merge or consolidate. The releases in Paragraphs 13 through 15 of this Agreement shall inure to the benefit of, and be enforceable by, the respective released persons described therein.

28. **Severability.** If any provision in this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall nevertheless continue in full force and continue to be binding on the Parties without being impaired or invalidated in any way.

29. **Notice/Cure/Settlement Conference.** Before raising any potential breaches of this Settlement with any court, the Parties will meet and confer within [*****] of notice of the breach to negotiate a resolution. Notice pursuant to this requirement shall be in writing and shall be deemed duly given: (i) upon actual receipt; (ii) [*****] after mailing by first class, certified, or registered U.S. mail, postage prepared and addressed as indicated in Paragraph 26, return receipt requested; (iii) if given by email, once such notice or other communication is transmitted to the email address(es) specified in this Settlement, or (iv) if sent through a nationally-recognized overnight delivery service

that guarantees next day delivery and addressed as indicated in this Settlement, the business day following its delivery to such service in time for next day delivery. The Party alleged to be in breach shall have [*****] in which to cure the breach. If no resolution can be negotiated or if the breach is not cured within [*****], or cannot be cured, the non-breaching Party may file an action seeking to enforce this Settlement.

30. **Enforcement.** Nothing herein shall be construed to limit or prejudice in any way any Party's rights to seek enforcement of the terms of this Agreement against the breaching Party, including specifically, rights to sue for breach of contract and for specific performance and/or to seek appropriate legal and/or equitable relief to enforce this Agreement. The Parties agree that any Party found to have breached this Agreement shall reimburse the non-breaching Party for the actual and reasonable attorneys' fees, costs, and expenses that the non-breaching Party incurs in connection with the enforcement of this Agreement or any claim, damages, or litigation relating to any breach of this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered as of the 13th day of July, 2024.

[SIGNATURE PAGES FOLLOW]

ALTOR BIOSCIENCE, LLC

By: /s/ Richard Adcock
Name: Richard Adcock
Title: President and Chief Executive Officer

NANTCELL, INC.

By: /s/ Richard Adcock
Name: Richard Adcock
Title: President and Chief Executive Officer

IMMUNITYBIO, INC.

By: /s/ Richard Adcock
Name: Richard Adcock
Title: President and Chief Executive Officer

HCW BIOLOGICS, INC.

By: /s/ Dr. Hing C. Wong
Name: Dr. Hing C. Wong
Title: Chief Executive Officer

DR. HING C. WONG

By: /s/ Dr. Hing C. Wong
Name: Dr. Hing C. Wong

Schedule 1
[*****]

[*****]

Schedule 2(a)(iii)
Know-How and Materials Transfer

[*****]

[6] [*****]

Schedule 3
Transferred Contracts

[*****]

Exhibit A

Wugen Agreement

[*****]

Exhibit B

Form of Patent Assignment

[*****]

Exhibit C

Power of Attorney

[*****]

Exhibit D

Form of EirGenix Letter

[*****]

Exhibit E

Form of Declaration

[*****]

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Richard Adcock, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ImmunityBio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 12, 2024

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer and President
(*Principal Executive Officer*)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, David C. Sachs, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ImmunityBio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 12, 2024

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Richard Adcock, the Chief Executive Officer of ImmunityBio, Inc. (the "Company"), hereby certify, that, to my knowledge:

i. the Quarterly Report of the Company on Form 10-Q for the quarter ended September 30, 2024 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 12, 2024

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer and President
(*Principal Executive Officer*)

EXHIBIT 32.2

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, David C. Sachs, the Chief Financial Officer of ImmunityBio, Inc. (the "Company"), hereby certify, that, to my knowledge:

i. the Quarterly Report of the Company on Form 10-Q for the quarter ended September 30, 2024 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 12, 2024

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial Officer)