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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2022**

or

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

For the transition period from _____ to _____

Commission File Number: **001-36374**

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

Delaware	**74-2963609**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
275 Madison Ave, 7th Floor New York, NY	**10016**
(Address of Principal Executive Offices)	(Zip Code)

(646) 677-3870
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common stock, par value $0.001	**ATNM**	**NYSE American**

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

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

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of August 12, 2022: 25,184,654

Actinium Pharmaceuticals, Inc.
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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared by the Company and are unaudited. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position at June 30, 2022 and December 31, 2021, and the results of operations and cash flows for the three and six months ended June 30, 2022 and 2021, respectively, have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the financial statements and notes thereto included in the Company's audited financial statements for the year ended December 31, 2021 in the Company's Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the operating results for the full year.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

	June 30, 2022 (Unaudited)	December 31, 2021 (Audited)
Assets		
Current Assets:		
Cash and cash equivalents	$ 116,330	$ 77,829
Restricted cash	392	392
Security deposit	50	50
Prepaid expenses and other current assets	1,525	1,478
Total Current Assets	118,297	79,749
Property and equipment, net of accumulated depreciation of $395 and $335	557	340
Security deposit – long term	299	-
Operating leases right-of-use assets	2,629	241
Finance leases right-of-use assets	18	58
Total Assets	**$ 121,800**	**$ 80,388**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,767	$ 5,535
Other revenue deferred– current liability	204	998
Operating leases current liability	292	245
Finance leases current liability	19	62
Total Current Liabilities	6,282	6,840
Long-term license revenue deferred	35,000	-
Long-term operating leases obligations	2,335	-
Long-term finance leases obligations	2	3
Total Liabilities	$ 43,619	$ 6,843
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 1,000,000,000 shares authorized; 24,870,623 and 22,143,974 shares issued and outstanding, respectively	25	22
Additional paid-in capital	346,800	329,271
Accumulated deficit	(268,644)	(255,748)
Total Stockholders' Equity	78,181	73,545
Total Liabilities and Stockholders' Equity	**$ 121,800**	**$ 80,388**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue				
Revenue	$ -	$ -	$ -	$ -
Other revenue	45	266	985	888
Total revenue	45	266	985	888
Operating expenses:				
Research and development, net of reimbursements	4,662	3,631	9,031	7,907
General and administrative	3,233	1,710	4,968	3,428
Total operating expenses	7,895	5,341	13,999	11,335
Loss from operations	(7,850)	(5,075)	(13,014)	(10,447)
Other income:				
Interest income - net	83	54	118	106
Total other income	83	54	118	106
Net loss	**$ (7,767)**	**$ (5,021)**	**$ (12,896)**	**$ (10,341)**
Net loss per common share – basic and diluted	$ (0.33)	$ (0.25)	$ (0.56)	$ (0.54)
Weighted average common shares outstanding – basic and diluted	23,731,886	20,231,278	22,942,317	19,308,487

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Three and Six Months Ended June 30, 2022
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2022	**22,143,974**	**$ 22**	**$ 329,271**	**$ (255,748)**	**$ 73,545**
Stock-based compensation	-	-	421	-	421
Net loss	-	-	-	(5,129)	(5,129)
Balance, March 31, 2022	**22,143,974**	**$ 22**	**$ 329,692**	**$ (260,877)**	**$ 68,837**
Stock-based compensation	-	-	425	-	425
Sale of common stock, net of issuance costs	2,726,649	3	16,683	-	16,686
Net loss	-	-	-	(7,767)	(7,767)
Balance, June 30, 2022	**24,870,623**	**$ 25**	**$ 346,800**	**$ (268,644)**	**$ 78,181**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Three and Six Months Ended June 30, 2021
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2021	**17,532,893**	**$ 18**	**$ 292,275**	**$ (230,974)**	**$ 61,319**
Stock-based compensation	-	-	376	-	376
Sale of common stock, net of costs	1,712,745	1	14,360	-	14,361
Net loss	-	-	-	(5,320)	(5,320)
Balance, March 31, 2021	**19,245,638**	**$ 19**	**$ 307,011**	**$ (236,294)**	**$ 70,736**
Stock-based compensation	8,705	-	459	-	459
Sale of common stock, net of issuance costs	1,835,688	2	14,317	-	14,319
Exercise of stock options	900	-	6	-	6
Net loss	-	-	-	(5,021)	(5,021)
Balance, June 30, 2021	**21,090,931**	**$ 21**	**$ 321,793**	**$ (241,315)**	**$ 80,499**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	For the Six Months Ended June 30,	
	2022	**2021**
Cash Flows From Operating Activities:		
Net loss	$ (12,896)	$ (10,341)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	846	835
Depreciation	317	254
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(47)	106
Payment of security deposit	(299)	-
Accounts payable and accrued expenses	232	(913)
Other revenue deferred– current liability	(794)	-
Long-term license revenue deferred	35,000	-
Operating lease liabilities	(222)	(167)
Net Cash Provided By/Used In Operating Activities	**22,137**	**(10,226)**
Cash Flows Used In Investing Activities:		
Purchase of property and equipment	(277)	(65)
Net Cash Used In Investing Activities	**(277)**	**(65)**
Cash Flows From Financing Activities:		
Payments on finance leases	(45)	(42)
Sales of shares of common stock, net of costs	16,686	28,680
Proceeds from exercise of stock options	-	6
Net Cash Provided By Financing Activities	**16,641**	**28,644**
Net change in cash, cash equivalents, and restricted cash	38,501	18,353
Cash, cash equivalents, and restricted cash at beginning of period	78,221	63,999
Cash, cash equivalents, and restricted cash at end of period	**$ 116,722**	**$ 82,352**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -

See accompanying notes to the condensed consolidated financial statements.

Note 1 - Description of Business and Summary of Significant Accounting Policies

Nature of Business - Actinium Pharmaceuticals, Inc. (the "Company" or "Actinium") is a clinical-stage, biopharmaceutical company focused on developing and potentially commercializing targeted radiotherapies for patients with unmet needs. The Company applies its proprietary technology platform consisting of over 195 patents and patent applications, know-how and clinical experience in approximately 600 patients to develop novel therapies for blood cancer and solid tumor indications. Its clinical and preclinical development programs utilize multiple isotopes including Actinium-225, Iodine-131 and Lutetium-177 directed at multiple validated cancer targets including CD45, CD33, CD38, CD47, HER2 and HER3 for targeted conditioning prior to cell and gene therapies including bone marrow transplant and cancer therapeutics as single agents or in combination with other therapeutic modalities.

Basis of Presentation - The accompanying unaudited condensed consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for condensed financial information, and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC") with respect to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of management, necessary for a fair statement of the results for the condensed periods presented. Condensed results are not necessarily indicative of the results for the full year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Principles of Consolidation - The basis of consolidation is unchanged from the disclosure in the Company's Notes to the Consolidated Financial Statements section in its Report on Form 10-K for the year ended December 31, 2021. The unaudited condensed consolidated financial statements include the Company's accounts and those of the Company's wholly owned subsidiaries.

Use of Estimates - The preparation of these unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Impact of COVID–19 Pandemic on Financial Statements - The global health crisis caused by the novel coronavirus ("COVID-19") pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, the Omicron variants of COVID-19, including subvariants BA.4 and BA.5, which appear to be the most transmissible variants to date, have spread globally. The full impact of the Omicron variants, or any subsequent variants, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Omicron variants and subsequent variants and the response by governmental bodies and regulators.

Many countries around the world have continued to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Accordingly, the Company's ability to continue to operate its business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect the Company's business, financial condition and results of operations. In response to COVID-19, the Company implemented hybrid working for its office-based staff, while its research staff has been actively working in its laboratory throughout the pandemic and thus far, has not experienced a significant disruption or delay in its operations as it relates to the clinical development, preclinical research or drug production of its drug candidates. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business and the value of the Company's common stock.

Additionally, COVID-19 may result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

To date, COVID-19 has not had a financial impact on the Company. The Company continues to monitor the impacts of COVID-19 on the global economy and on its business operations. However, at this time, it is difficult to predict how long the potential operational impacts of COVID-19 will last or to what degree further disruption might impact the Company's operations and financial results.

Cash, Cash Equivalents and Restricted Cash - The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents. Balances held by the Company are typically in excess of Federal Deposit Insurance Corporation insured limits.

The following is a summary of cash, cash equivalents and restricted cash at June 30, 2022 and December 31, 2021:

(in thousands)	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 116,330	$ 77,829
Restricted cash	392	392
Cash, cash equivalents and restricted cash	$ 116,772	$ 78,221

Restricted cash relates to a certificate of deposit held as collateral for a letter of credit issued in connection with the Company's lease for corporate office space.

Leases – The Company has operating and finance leases for corporate office space, office equipment and furniture located at the corporate office space. Leases with an initial term of 12 months or less are not recorded on the balance sheet; lease expense for these leases is recognized on a straight-line basis over the lease term. The Company entered into a lease for corporate office space effective June 1, 2022 and paid a security deposit to the landlord. A certificate of deposit will be provided as collateral for a letter of credit to be issued with this new office space during 2022 and at that time, the security deposit will be returned to the Company.

Revenue Recognition - The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue From Contracts With Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue as the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the promised goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. In determining whether goods or services are distinct, the Company evaluates certain criteria, including whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (capable of being distinct) and (ii) the good or service is separately identifiable from other goods or services in the contract (distinct in the context of the contract).

The Company then determines the transaction price, which is the amount of consideration it expects to be entitled from a customer in exchange for the promised goods or services for each performance obligation and recognizes the associated revenue as each performance obligation is satisfied. The Company's estimate of the transaction price for each contract includes all variable consideration to which it expects to be entitled. Variable consideration includes payments in the form of collaboration milestone payments. If an arrangement includes collaboration milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price.

ASC 606 requires the Company to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in the revenue standard as the price at which an entity would sell a promised good or service separately to a customer. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Collaborative Arrangements - The Company follows the accounting guidance for collaboration agreements with third parties, which requires that certain transactions between the Company and collaborators be recorded in its consolidated statements of operations and comprehensive loss on either a gross basis or net basis, depending on the characteristics of the collaborative relationship, and requires enhanced disclosure of collaborative relationships. The Company evaluates its collaboration agreements for proper classification in its consolidated statements of operations and comprehensive loss based on the nature of the underlying activity. When the Company has concluded that it has a customer relationship with one of its collaborators, the Company follows the guidance of ASC 606.

Grant Revenue – The Company has a grant from a government-sponsored entity for research and development related activities that provides for payments for reimbursed costs, which includes overhead and general and administrative costs as well as an administrative fee. The Company recognizes revenue from grants as it performs services and all conditions are met under this arrangement. Associated expenses are recognized when incurred as research and development expense. Revenue and related expenses are presented gross in the consolidated statements of operations.

License Revenue – The Company entered into a product licensing agreement whereby the Company allowed a third party to commercialize a certain product in specified territories using the Company's trademarks. The terms of this arrangement includes payment to the Company for a combination of one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; and royalties on net sales of licensed products. The Company uses its judgment to determine whether milestones or other variable consideration should be included in the transaction price.

Upfront license fees: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time.

Development, regulatory or commercial milestone payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and sales-based or commercial events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until regulatory approval is received. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of license revenue during the period of adjustment.

Sales-based milestone payments and royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the Company will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements or when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur or when the uncertainty associated with any variable consideration is subsequently resolved. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Costs - Research and development costs are expensed as incurred. These costs include the costs of manufacturing drug product, the costs of clinical trials, costs of employees and associated overhead, and depreciation and amortization costs related to facilities and equipment. Research and development reimbursements are recorded by the Company as a reduction of research and development costs.

Share-Based Payments - The Company estimates the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. The Company accounts for forfeitures of stock options as they occur.

Net Loss Per Common Share - Basic loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the reporting period. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive. For the three months ended June 30, 2022 and 2021, the Company's potentially dilutive shares, which include outstanding common stock options and warrants, have not been included in the computation of diluted net loss per share as the result would have been anti-dilutive.

(in thousands)	**June 30, 2022**	**June 30, 2021**
Options	1,431	859
Warrants	2,053	2,114
Total	3,484	2,973

Recently Adopted Accounting Pronouncements – In May 2021, FASB issued ASU 2021-04, *Earnings Per Share (topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718) and Derivatives and Hedging – Contracts in an Entity's Own Equity (Subtopic 815-40) – Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, which provides guidance of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU are effective January 1, 2022, including interim periods. The Company adopted this standard effective January 1, 2022 and the standard did not have a material effect on the Company's financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance*, which provides guidance on disclosure requirements to entities other than not-for-profit entities about transaction with a government that are accounted for by applying a grant or contribution accounting model by analogy. ASU 2021-10 requires an entity to make annual disclosures related to (1) the nature of the transactions and the related accounting policy used to account for the government transactions, (2) quantification and disclosure of amounts related to the government transactions included in balance sheet and income statement financial statement line items, and (3) significant terms and conditions of the government transactions, including commitments and contingencies. The amendments of ASU 2021-10 are effective January 1, 2022, including interim periods. The Company adopted this standard effective January 1, 2022, and the standard did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements – In October 2021, FASB issued ASU 2021-08, *Business Combinations (Topic 805), Account for Contract Assets and Contract Liabilities from Contracts with Customers*, which provides guidance on accounting for contract assets and contract liabilities acquired in a business combination in accordance with ASC 606. To achieve this, an acquirer may assess how the acquiree applied ASC 606 to determine what to record for the acquired revenue contracts. Generally, this should result in an acquirer recognizing and measuring the acquired contract assets and contract liabilities consistent with how they were recognized and measured in the acquiree's financial statements. The amendments of ASU 2021-08 are effective January 1, 2023, including interim periods. Early adoption is permitted, including adoption in an interim period. The Company will evaluate the impact of ASU 2021-08 on any future business combinations the Company may enter in the future.

Note 2 - Commitments and Contingencies

On June 15, 2012, the Company entered into a license and sponsored research agreement with Fred Hutchinson Cancer Research Center ("FHCRC") to build upon previous and ongoing clinical trials with apamistamab (licensed antibody). FHCRC has completed both a Phase 1 and Phase 2 clinical trial with apamistamab. The Company has been granted exclusive rights to the antibody and related master cell bank developed by FHCRC. A milestone payment of $1 million will be due to FHCRC upon U.S. Food and Drug Administration ("FDA") approval of the first drug utilizing the licensed antibody. Upon commercial sale of the drug, royalty payments of 2% of net sales will be due to FHCRC.

Note 3 - Leases

The Company entered into a lease for corporate office space, effective June 1, 2022. As of June 30, 2022, the Company has two operating leases for corporate office space and two finance leases for office equipment and furniture located in one of the corporate office spaces. In addition, the Company has auxiliary corporate office space that it rents on a month-to-month basis; this rental is accounted for as an operating lease with the same term as the Company's main office.

The components of lease expense are as follows:

	Three months ended		Six months ended	
(in thousands)	**June 30, 2022**	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Operating lease expense	$ 141	$ 93	$ 234	$ 186
Finance lease cost				
Amortization of right-to-use assets	$ 20	$ 21	$ 41	$ 41
Interest on lease liabilities	$ 1	$ 2	$ 2	$ 5
Total finance lease cost	$ 21	$ 23	$ 43	$ 46

Supplemental cash flow information related to leases are as follows:

Cash flow information:

	Six months ended	
(in thousands)	**June 30, 2022**	**June 30, 2021**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow use from operating leases	$ 239	$ 188
Operating cash flow use from finance leases	$ 2	$ 5
Financing cash flow use from finance leases	$ 45	$ 42
Non-cash activity:		
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 2,605	$ -
Finance Leases	$ -	$ -

Weighted average remaining lease terms are as follows at June 30, 2022:

Weighted average remaining lease term:	
Operating leases	5.0 years
Finance Leases	0.5 year

As the interest rate implicit in the leases was not readily determinable at the time that the leases were evaluated, the Company used its incremental borrowing rate based on the information available in determining the present value of lease payments. The Company's incremental borrowing rate was based on the term of the lease, the economic environment of the lease and reflect the rate the Company would have had to pay to borrow on a secured basis. Below is information on the weighted average discount rates used at the time that the leases were evaluated:

Weighted average discount rates:	
Operating leases	4.8%
Finance Leases	8.0%

Maturities of lease liabilities are as follows:

(in thousands) **Year ending December 31,**	**Operating Leases**	**Finance Leases**
2022 (excluding six months ended June 30, 2022)	$ 113	$ 17
2023	606	5
2024	618	-
2025	630	-
2026	643	-
2027	380	-
Total lease payments	$ 2,990	$ 22
Less imputed interest	(363)	(1)
Present value of lease liabilities	$ 2,627	$ 21

Note 4 – Other revenue

The Company determined that certain collaborations with a third party are within the scope of ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. The Company identified a single performance obligation to provide research services within each module for which the Company receives monetary consideration. The third party can choose to proceed with each module or can terminate the agreement at any time. The Company recognizes revenue for each module on a straight-line basis over the expected module period. Revenue for succeeding modules is not recognized until all contingencies are resolved, inclusive of the third party's ability to terminate the module. Other revenue recognized during the three months and six months ended June 30, 2022 was $0.0 million and $0.9 million, respectively, and for the three months and six months ended June 30, 2021 was $0.3 million and $0.9 million, respectively.

The Company has a grant from a government-sponsored entity for research and development related activities that provide for payments for reimbursed costs, which includes overhead and general and administrative costs as well as an administrative fee. The Company recognizes revenue from grants as it performs services under this arrangement. Associated expenses are recognized when incurred as research and development expense. Other revenue recognized during the three months and six months ended June 30, 2022 was $0.0 million and $0.1 million, respectively. There was no other revenue recognized from a grant from a government-sponsored entity during the six months ended June 30, 2021.

On April 7, 2022, the Company entered into a license and supply agreement (the "License Agreement") with Immedica Pharma AB ("Immedica"), pursuant to which Immedica licensed the exclusive product rights for commercialization of Iomab-B (I-131 apamistamab) in the European Economic Area, Middle East and North Africa (EUMENA) including Algeria, Andorra, Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Monaco, Morocco, Oman, Palestine, Qatar, San Marino, Saudi Arabia, Switzerland, Syria, Tunisia, Turkey, the United Arab Emirates, the United Kingdom, the Vatican City and Yemen. Upon signing, the Company was entitled to an upfront payment of $35 million from Immedica, which was received in May 2022. Under the terms of the License Agreement, the Company is eligible to receive regulatory and commercial milestone payments and is entitled to receive royalties in the mid-20 percent range on net sales of the product in certain countries that may result from the License Agreement. The Company will continue to be responsible for certain clinical development activities and the manufacturing of Iomab-B and will retain commercialization rights in the U.S. and rest of the world.

The Company's contract liabilities are recorded within Other revenue deferred – current liability or Long-term license revenue deferred in its condensed consolidated balance sheets depending on the short-term or long-term nature of the payments to be recognized. The Company's contract liabilities primarily consist of advanced payments from licensees. Other revenue deferred – current liability was $0.2 million at June 30, 2022 and $0.9 million at December 31, 2021. Long-term license revenue deferred was $35.0 million at June 30, 2022; there was no long-term license revenue deferred at December 31, 2021. This deferred revenue will be recognized upon EU regulatory approval of Iomab B.

Note 5 - Equity

In August 2020 the Company entered into the Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which the Company may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of its common stock. Shares of common stock are offered pursuant to a shelf registration statement on Form S-3 filed with the SEC on August 7, 2020. As of December 31, 2021, the Company had sold 6.7 million shares of common stock, resulting in gross proceeds of $59.1 million and net proceeds of $57.0 million. For the six months ended June 30, 2022, the Company sold 2.7 million shares of common stock, resulting in gross proceeds of $17.2 million and net proceeds of $16.7 million. For the six months ended June 30, 2021, the Company sold 3.5 million shares of common stock, resulting in gross proceeds of $29.6 million and net proceeds of $28.7 million.

On June 28, 2022, the Company entered into an Amendment and Restated Capital on Demand™ Sales Agreement (the "A&R Sales Agreement") with JonesTrading and B. Riley Securities, Inc. ("B. Riley Securities"). The A&R Sales Agreement modifies the original Capital on Demand™ Sales Agreement to include B. Riley Securities as an additional sales agent thereunder.

Stock Options

The following is a summary of stock option activity for the six months ended June 30, 2022:

(in thousands, except for per-share amounts)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	1,362	$ 12.45	8.69	$ -
Granted	120	5.23		
Cancelled	(51)	8.89		
Outstanding, June 30, 2022	1,431	11.97	8.36	-
Exercisable, June 30, 2022	473	22.19	7.07	-

During the six months ended June 30, 2022, the Company granted new employees options to purchase 120 thousand shares of common stock with an exercise price ranging from $5.20 to $5.93 per share, a term of 10 years, and a vesting period of 4 years. The options have an aggregated fair value of $442 thousand that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 1.52% to 3.03% (2) expected life of 6 years, (3) expected volatility range from 78.8% to 79.9%, and (4) zero expected dividends.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at June 30, 2022 was $4.4 million related to unvested options, which is expected to be expensed over a weighted average of 3.0 years. During the six months ended June 30, 2022 and 2021, the Company recorded compensation expense related to stock options of $0.8 million and $0.7 million, respectively.

Warrants

Following is a summary of warrant activity for the six months ended June 30, 2022:

(in thousands, except for per-share amounts)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	2,112	$ 20.52	1.76	$ 276
Granted	-	-		
Exercised	-	-		
Cancelled/Expired	(59)	3.62		
Outstanding, June 30, 2022	2,053	$ 21.01	1.32	$ -
Exercisable, June 30, 2022	2,049	$ 20.57	1.31	$ -

Note 6 – Subsequent Event

Since June 30, 2022, the Company has sold 0.3 million shares of common stock under its A&R Sales Agreement, resulting in net proceeds of $1.4 million.

On August 2, 2022, warrants to purchase an aggregate of 0.6 million shares of common stock expired. These warrants were issued on August 2, 2017, when the Company completed an underwritten offering of 0.7 million shares of its common stock and warrants to purchase an aggregate of 0.6 million shares of its common stock at a price of $22.50 per share and related warrant. The warrants were exercisable for a period of 5 years at an exercise price of $31.50 per share. As of August 12, 2022, the Company has 1.4 million warrants outstanding.

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

FORWARD-LOOKING STATEMENT NOTICE

This Form 10-Q contains certain forward-looking statements. For this purpose, any statements contained in this Form 10-Q that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "estimate" or "continue" or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, many of which are not within our control. These factors include but are not limited to economic conditions generally and in the industries in which we may participate; competition within our chosen industry, including competition from much larger competitors; technological advances and failure to successfully develop business relationships.

Description of Business

Actinium Pharmaceuticals, Inc. is a clinical-stage, biopharmaceutical company applying its proprietary platform technology and deep understanding of radiobiology to the development of novel targeted radiotherapies for patients with unmet needs. Our targeted radiotherapies combine the cell-killing ability of radiation via a radioisotope payload with a targeting agent, such as a monoclonal antibody, to deliver radiation in a precise manner inside the body to specific, targeted cells, to potentially achieve greater efficacy with lower toxicity than with external beam radiation. They also enable a broader usage of radiation than external beam radiation as they can be used in the treatment of both solid tumors and blood cancers, which generally cannot be treated with external radiation given their diffuse nature. Our clinical pipeline is focused on targeting the antigens CD45 and CD33, both of which are expressed in multiple hematologic cancers, which are known to be highly sensitive to radiation. Our clinical programs are focused on two primary areas: (1) targeted conditioning prior to a bone marrow transplant ("BMT"), adoptive cell therapy ("ACT") such as CAR-T or gene therapy with Iomab-B and (2) targeted radiotherapy combinations with Actimab-A and other therapeutic agents. Our product development strategy is actively informed by clinical data with Iomab-B and Actimab-A in approximately 600 patients, including our ongoing Pivotal Phase 3 SIERRA trial, which completed its targeted enrollment of 150 patients in the third quarter of 2021, with the last patient receiving their BMT in the fourth quarter of 2021. Our clinical pipeline has emanated from our Antibody Warhead Enabling ("AWE") technology platform, which is protected by over 195 issued and pending patents, trade secrets and know-how that we are applying to the development of targeted radiotherapies for blood and solid tumor indications, independently and with collaborators. Ongoing collaborations include a research partnership with Astellas Pharma, Inc. ("Astellas") focused on the development of theranostics, which enable the diagnosis and treatment, for solid tumor indications, a collaboration with EpicentRx, Inc, focused on a novel CD47 immunotherapy targeted radiotherapy combination, leveraging EpicentRx's RRx-001, that is being studied in a Phase 3 trial in non-small cell lung cancer, with our clinical stage Actimab-A in AML models, and a collaboration with AVEO Oncology, focused on developing a HER3 targeting ARC or Antibody Radiation Conjugate for solid tumors leveraging with their clinical stage antibody. We are also utilizing our AWE technology platform to advance our research objectives focused on developing next-generation targeted radiotherapies with our expanded research and development organization and research laboratories leveraging our drug development experience.

Targeted Conditioning

To the best of our knowledge, we are advancing the most advanced multi-target, multi-indication, clinical-stage pipeline for targeted conditioning. Our targeted conditioning agents are intended to potentially enable improved access and outcomes to cell-based therapies with curative potential, including BMT, ACT and gene therapy. Conditioning in the context of BMT, ACT or gene therapy is the act of depleting certain blood and immune-forming cells, including bone marrow stem cells and, in some cases, cancer cells prior to transplanting new cells into a patient. Currently, conditioning is accomplished using a combination of cytotoxic chemotherapeutic agents and external radiation. These non-targeted conditioning regimens are highly toxic and may prevent a patient from receiving a potentially curative therapy and hinder outcomes. We believe our targeted conditioning agents have the potential to increase patient access and outcomes by way of their ability to selectively deplete targeted cells while sparing normal healthy cells, resulting in potentially lower systemic and off-target toxicities. We use our ARCs both at high isotope dose levels to achieve myeloablation, which fully depletes bone marrow stem cells and at lower isotope dose levels to achieve lymphodepletion, which spares bone marrow stem cells from depletion. In addition, dosing may be titrated downward from myeloablative doses to achieve partial myeloablation, which may be appropriate for certain gene therapy programs.

CD45 Targeted Conditioning Program

Iomab-B (I-131 apamistamab), our lead candidate and targeted conditioning agent is comprised of the anti-CD45 monoclonal antibody known as apamistamab (formerly BC8) and the radioisotope Iodine-131 ("I-131"). CD45 is an antigen expressed on leukemia, lymphoma and myeloma cancer cells, as well as nucleated immune cells including bone marrow stem cells, but is not expressed outside of the hematopoietic, or blood forming, system. This unique expression on blood cancer and immune cells enables simultaneous depletion of both cell types, making CD45 an optimal antigen for targeted conditioning applications. CD45 is a cell surface antigen with an average expression of 200,000 copies per cell, however, it only internalizes at a rate of 10-15%. We believe our ARC approach is the most effective method to target CD45 positive cells, as the radioisotope payload linear energy transfer can readily ablate a targeted cell without requiring payload internalization like an antibody drug conjugate or without relying on biological effector function processes like a naked antibody. Furthermore, since CD45 expression level varies from low to high antigen density as the immune cells become more terminally differentiated, we can selectively condition depending on the therapeutic application, from full myeloablation to transient lymphodepletion, by adjusting the dose or intensity of the I-131 isotope payload. Full myeloablation can be achieved with high doses of I-131, as its energy pathlength and crossfire effect can penetrate into bone marrow niches to target and deplete blood and immune system forming bone marrow stem cells. Myeloablation is applicable to autologous or allogeneic BMT and to autologous gene-edited or modified therapies that can reconstitute a patient's blood and immune systems. Alternatively, low doses of I-131 can be transiently lymphodepleting and spare a patient's bone marrow stem cells, which we believe is ideal for ACT applications such as CAR-T. We intend to develop our CD45 targeted conditioning program for BMT, ACT and gene therapy applications for malignant and non-malignant diseases and believe that multiple radioisotopes beyond I-131 may be utilized including alpha and beta emitters.

Iomab-B uses high doses of I-131 to achieve myeloablative conditioning prior to a BMT. Iomab-B is currently being studied in the pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory AML ("SIERRA"), clinical trial for targeted conditioning prior to an allogeneic BMT for patients with active, relapsed or refractory ("r/r") Acute Myeloid Leukemia, ("AML"), who are age 55 or older. Enrollment of the planned 150 patients in the SIERRA trial was completed in the third quarter of 2021 with the last patient receiving their BMT in the fourth quarter of 2021. Patients with active, r/r AML are not normally considered eligible for BMT and the SIERRA trial is the only randomized Phase 3 trial to offer BMT as a treatment option for this patient population. The SIERRA trial compares outcomes of patients randomized to receive Iomab-B and a BMT (the "study arm") to those patients randomized to receive physician's choice of salvage therapy (the "control arm"). The control arm is also defined as conventional care, as no standard of care exists for this patient population and includes over 20 agents that may be used as single agents or in combination including venetoclax, a targeted Bcl-2 inhibitor, Midostaurin and Sorafenib, targeted FLT3 inhibitors, hypomethylating agents and cytotoxic chemotherapies. Patients who fail to achieve a Complete Remission ("CR") on the control arm are ineligible to proceed to a BMT, but the trial design permits these patients to "cross over" to receive the study arm treatment if they meet the eligibility criteria. The primary endpoint of the SIERRA trial is durable Complete Remission ("dCR") of 180 days and the secondary endpoint is Overall Survival ("OS"). When the crossover patients receive Iomab-B and BMT, they have not achieved remission with their salvage therapy and are considered to be failures for the primary endpoint of the study. The SIERRA trial recruited patients at 24 sites in the United States and Canada, which includes many of the leading BMT sites based on volume.

If approved, we expect our initial commercial launch would target the leading 50-100 BMT and medical centers that perform the vast majority of BMTs in the United States. In the European Union ("EU"), we received favorable feedback from the European Medicines Agency ("EMA") via their scientific advice program that the trial design, primary endpoint and planned statistical analysis from the SIERRA trial are acceptable as the basis for a Marketing Authorization Application, or MAA. Additionally, the EMA commented that it does not anticipate the need for further standalone preclinical toxicology or safety studies. Overall, transplant procedures in the EU are approximately fifty percent higher than in the United States with a similar market dynamic, with a majority of BMT volume being conducted in a concentrated number of leading medical centers. In April 2022, we entered into a license and supply agreement with Immedica Pharma AB, or Immedica, pursuant to which Immedica licensed the exclusive product rights for commercialization of Iomab-B in the European Economic Area, Middle East and North Africa. including Algeria, Andorra, Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya. Monaco, Morocco, Oman, Palestine, Qatar, San Marino, Saudi Arabia, Switzerland, Syria, Tunisia, Turkey, the United Arab Emirates, the United Kingdom, the Vatican City and Yemen. Upon signing, we were entitled to an upfront payment of $35 million from Immedica, which we received in May 2022. Under the terms of the agreement, we are eligible to receive regulatory and commercial milestone payments and we are entitled to receive royalties in the mid-20 percent range on net sales of the product in certain countries that may result from the License Agreement. We will continue to be responsible for certain clinical development activities and the manufacturing of Iomab-B and will retain commercialization rights in the U.S. and rest of the world.

Data from full patient enrollment in the SIERRA trial (153 patients), was presented at the Transplantation & Cellular Therapy (TCT) Tandem Meetings of ASTCT and CIBMTR, the combined annual meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) in April 2022. The data presented includes rates of BMT access and engraftment, 100-day non-relapse transplant-related mortality (100-day TRM) and adverse events, which has been reported from interim analyses conducted at 25%, 50%, 75% and 100% of patient enrollment pursuant to the study protocol. The data presented at ASH highlighted that 100% of patients (66/66) on the study arm that received a therapeutic dose of Iomab-B received a BMT, with a median time to BMT of 30 days, and all patients achieved neutrophil and platelet engraftment in a median time of 18 days despite a high median blast count of 30%. On the control arm, only 18% of patients (14/77) achieved remission after salvage therapy, and then received a BMT with a median time to BMT of 67 days and median blast count of 20%. Of the 82% of patients failing to achieve a complete remission ("CR") with conventional care (63/77), 40 patients were eligible and elected to cross over to receive Iomab-B followed by transplant. These patients are considered as having failed the primary endpoint of the study. All crossover patients who received the therapeutic dose of Iomab-B (40/40) received a BMT, with a median time to BMT of 24 days and they achieved engraftment in a median time of 19 days despite high median blast count of 35% at time of crossover. It was also reported that 100-day TRM of the study or Iomab-B arm was 09% (6/65) of patients that received a BMT compared to 14% of patients (2/14) who received a BMT after salvage therapy on the control arm. The universal engraftment rate and low 100-day TRM rate of the Iomab-B arm resulted in 59 patients potentially evaluable for the primary endpoint compared to 12 patients in the control arm, an approximate five times difference. At each of the interim analyses throughout the SIERRA trial, this approximate five times difference has been consistent in favor of the Iomab-B arm as a result of higher rates of BMT engraftment and lower rates of 100-day TRM. Top-line data for the primary endpoint of durable Complete Remission is expected to be presented in the fourth quarter of 2022 based on the current status of the data collection and data query process with certain SIERRA trial sites. We believe topline data from SIERRA will support the submission of a Biologics License Application ("BLA") with the FDA, which we expect to file in the first half of 2023.

Our Iomab-ACT program is intended for targeted conditioning prior to ACT or gene therapy and uses the same I-131-apamistamab construct as Iomab-B at varying doses. At lower doses of one-eighth to one-sixth of the myeloablative dose, it is applicable for lymphodepletion prior to CAR-T or certain gene therapy applications where stem cell myeloablation is not necessary. At higher doses it is applicable for gene therapy applications where stem cell myeloablation is necessary.

We believe our Iomab-ACT program is highly differentiated when compared to Fludarabine and Cyclophosphamide ("Flu/Cy") or other chemotherapy-based regimens that are used as the standard of practice today for lymphodepletion prior to CAR-T. CD45 is an antigen expressed on certain immune cell types that are relevant to the mechanism of CAR-T therapies including lymphocytes, regulatory T-cells and macrophages that have been associated with clinical responses that may limit the safety, efficacy and durability of response of these CAR-T therapies including cytokine release syndrome ("CRS") and neurotoxicity. Some of these limitations may be attributable to the chemotherapy-based conditioning agents that are being used prior to CAR-T therapies. Preclinical data supporting the rational for our Iomab-ACT program was presented at multiple medical conferences in 2019. Unlike chemotherapy, Iomab-ACT is targeted in nature and, due to this CD45-directed targeting, we expect we can improve CAR-T cell expansion, potentially resulting in responses that are more durable, but also resulting in reduced CAR-T related toxicities. Importantly, we expect the Iomab-ACT program construct to enable lymphodepletion through a single-dose, outpatient administration versus Flu/Cy or other chemotherapy-based lymphodepletion regimens that can require multiple infusion cycles over several days. Because of this potentially superior profile, the Iomab-ACT construct could result in improved access to CAR-T therapy and better outcomes.

We are studying Iomab-ACT in a clinical collaboration with Memorial Sloan Kettering Cancer Center ("MSKCC") for targeted conditioning prior to administration of MSKCC's 19-28z CD19 targeting CAR-T in patients with relapsed or refractory B-cell acute lymphoblastic leukemia ("ALL") or diffuse large B-cell lymphoma ("DLBCL"). We received grant funding from the National Institute of Health ("NIH") to fund this trial with MSKCC being a co-recipient on this grant. This is a first of its kind study to use an ARC-based conditioning regimen with CAR-T therapy. The hypothesized rationale for this study is that Iomab-ACT will exert an anti-tumor effect on the chemotherapy-refractory B-ALL cells that are sensitive to radiation resulting in reduced disease burden and simultaneously deplete CD45 expressing immune cells implicated in CAR-T related toxicities, resulting in an optimal homeostatic environment for the CAR-T cells. Results with MSKCC's 19-28z CD-19 CAR-T in 53 patients with r/r B-ALL published in the New England Journal of Medicine reported complete remissions in 83% (44/53) of patients, which compares favorably to standard chemotherapy regimens that have complete remission rates of 18% - 45% in this patient population. Median event-free survival ("EFS") was 6.1 months and median overall survival ("OS") was 12.9 months at a median follow up period of 29 months (range 1 – 65 months). There was a 26% (14/53) rate of Grade 3 or greater CRS and a 42% rate of Grade 3 or 4 neurotoxicity reported. The study will evaluate the feasibility of using an ARC-based conditioning regimen with CAR-T therapy and will evaluate safety measures including incidence of CRS and neurotoxicity and efficacy measures including responses and survival outcomes. We expect proof of concept data from this study in the second half of 2022.

In addition, we are working in collaboration with the University of California Davis to utilize Iomab-ACT conditioning with a novel anti-HIV autologous gene therapy. We continue to identify additional gene therapies for which Iomab-ACT can be used for targeted conditioning with the goal of collaborating with multiple academic or industry developers to establish Iomab-ACT as a non-chemotherapy universal targeted conditioning solution.

CD33 Program: Combinations and Therapeutics

Our CD33 program is evaluating the clinical utility of Actimab-A, comprised of the anti-CD33 mAb lintuzumab linked to the potent alpha-emitting radioisotope Actinium-225 ("Ac-225"). CD33 is expressed in the majority of patients with AML and myelodysplastic syndrome ("MDS") as well as approximately one-third of patients with multiple myeloma. Ac-225 emits four alpha particles and can kill a cell with one alpha-particle hit, making it one of the most powerful cell-killing agents with no know resistance mechanism to the double strand DNA breaks it can cause. We source Ac-225 from the Department of Energy's Oak Ridge National Laboratory.

Our CD33 development program is driven by data obtained from over one hundred fifty treated patients, including results from a Phase 1/2 trial that studied Actimab-A as a single agent at multiple dose levels in 58 patients with newly diagnosed AML, which was completed in 2018, as well as trials studying Actimab-A in combination with other agents.

We believe that radiation delivered internally via a targeting moiety can be synergistic when used in combination with chemotherapy, targeted agents and immunotherapy based on mechanistic rationales supported by our own clinical data, preclinical research and scientific and clinical evidence in the literature. We have prioritized our efforts and resources in favor of combination trials for our CD33 program development strategy rather than single agent trials at this time as we believe Actimab-A can be a backbone therapy in AML when combined with other therapeutic modalities. Our CD33 development program encompasses the following ongoing trials:

Actimab -A Combination Trials:

Actimab-A + CLAG-M

The combination of Actimab-A with CLAG-M has been studied in a Phase 1 combination trial that was conducted in collaboration with the Medical College of Wisconsin ("MCW") in patients age 18 and above with r/r AML who are fit for intensive therapy. Patient enrollment was completed in November 2021. CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) is a salvage chemotherapy regimen that produced a 55% remission rate in patients with r/r AML in a previous study conducted by MCW that compared outcomes of patients receiving either CLAG-M, MEC or CLAG salvage therapy regimens. Data from the Phase 1 combination trial of Actimab-A + CLAG-M were presented at ASH in December 2021. After completion of dose-escalation in the Phase 1 trial, the recommended Phase 2 dose was determined to be 0.75 µCi/kg of Actimab-A. 3 patients were enrolled in the 0.75 µCi/kg dose cohort, which had a 100% remission rate comprised of 1 complete remission ("CR") and 2 complete remissions with incomplete platelet recovery ("CRp"), there were no dose limiting toxicities ("DLTs") or 30-day mortality reported. Overall, a 67% (12/18) overall response rate ("ORR") was reported across all dose cohorts (0.25 – 1.0 µCi/kg) and remissions were achieved in every dose cohort including the 0.25 and 0.50 µCi/kg doses of Actimab-A, which have been shown to be subtherapeutic as a single agent. In addition, there was a 72% minimal residual disease ("MRD") negativity rate, which compares favorably to the 39% MRD negativity rate reported by MCW with CLAG-M alone. This study enrolled patients who previously failed Venetoclax, a targeted Bcl-2 inhibitor, and efficacy was similar in patients Venetoclax naïve and those that previously failed Venetoclax, with a 60% response rate in previous Venetoclax failures. We are working to develop a regulatory and development pathway for the Actimab-A CLAG-M combination and will be evaluating potential registration enabling strategies. In addition, we believe this Actimab-A + CLAG-M combination study has provided proof of principle that the addition of Actimab-A to other AML therapies can lead to well-tolerated regimens with improved responses, which supports our Actimab-A backbone therapy in AML strategy.

Actimab-A + Venetoclax

We are also conducting a Phase 1/2 Actimab-A combination trial with the Bcl-2 inhibitor Venetoclax in fit and unfit patients age 18 and above with relapsed or refractory AML. This multi-center trial is being led by UCLA Medical Center. This combination is supported by mechanistic evidence in preclinical studies using Venetoclax - resistant AML tumor cell lines. In these models, we have demonstrated that Actimab-A can deplete Mcl-1 and Bcl-XL, two proteins implicated in mediating resistance to Venetoclax, in addition to causing potentially lethal double-stranded DNA breaks in these CD33 expressing cells. Furthermore, in vivo studies in animal models of Venetoclax-resistant AML demonstrated robust tumor regression and improved survival in cohorts receiving the Actimab-A Venetoclax combination compared to Venetoclax alone. The rationale for this clinical study is that the addition of Actimab-A will; 1) have a direct anti-tumor effect via double-stranded DNA breaks and 2) deplete Mcl-1 and Bcl-XL making the AML cells more susceptible to Venetoclax. Updated data from the Phase 1 dose escalation portion of this study was presented at ASH in December 2021 from three dose cohorts of 0.50, 0.75 and 1.0 μCi/kg of Actimab-A in a total of 12 patients. 50% of patients received Venetoclax therapy prior to enrollment on the Actimab-A combination trial. And 67% of patients had poor risk cytogenetics, of which, 3 had a TP53 mutation, which is associate with poorer response rates and survival outcomes. Of the patients with a TP53 mutation, 67% achieved a remission including a patient that achieved a CR who remained in follow-up 230 days (~7.5 months) at the time of data cutoff for ASH. The combination of Actimab-A with Venetoclax was reported to be well-tolerated with no 30-day mortality. The data to date support advancing to the Phase 2 portion of the trial and we expect to provide an update on the development strategy after the Phase 1 dose finding portion of the trial is complete and the recommended Phase 2 dose is determined.

In addition to these ongoing trials, we actively seek and evaluate additional modalities and agents that can be the basis for Actimab-A therapeutic combinations such as the CD47 immunotherapy magrolimab combinations we announced at the Society for Immunotherapy of Cancer (“SITC”) in November 2021 to leverage our clinical experience, supply chain and AWE technology platform.

CD47 Based ARC Combinations in Solid Tumors and Blood Cancers

CD47 is a macrophage checkpoint that is upregulated in multiple cancers including blood cancers such as AML and MDS as well as solid tumors. CD47 acts as a “don’t eat me” signal on cancer cells to suppress phagocytosis and evade detection and destruction by the immune system. It has become an immunotherapy target of significant interest with multiple biopharmaceutical companies actively developing CD47 targeting agents across a wide range of oncology and hematology indications. CD47 targeting agents have shown limited efficacy as single agent monotherapies in AML/MDS or solid tumors, which has led to combinations such as with hypomethylating agents in AML/MDS. We hypothesized that targeted radiotherapy via ARCs could synergize with CD47 targeting agents via the direct cytotoxic and immunogenic effect of ARCs without overlapping toxicities. To explore this synergy and the potential to improve patient outcomes and we have initiated a program in AML with our Actimab-A ARC, consistent with our strategy to establish Actimab-A as a backbone AML therapy, and in solid tumors with a HER2 and HER3 targeting ARCs, which emanated from our AWE technology platform. To our knowledge, these are the first and only ARC-based targeted radiotherapy combinations with CD47 immunotherapy. Data from the novel HER2 magrolimab combination was presented at the 36th Annual SITC Meeting in April 2022 and at the HER3 magrolimab combination was presented American Association for Cancer Research (“AACR”) Annual Meeting in April 2022 that showed a significant increase in tumor control compared to magrolimab alone in preclinical non-small cell lung cancer (“NSCLC”)

The most advanced CD47 development programs are being studied in patients with AML and MDS. Leveraging our clinical experience with Actimab-A in these indications we have begun studying Actimab-A with the anti-CD47 antibody immunotherapy magrolimab, which is owned by Gilead Sciences, Inc., in preclinical models of AML. In preclinical models, it was shown that in multiple AML cell lines, the combination of Actimab-A with magrolimab led to increased phagocytosis of AML cells compared to magrolimab alone. Our studies also demonstrated that AML cell lines exposed to Actimab-A had an upregulation of calreticulin, which is a pro-phagocytic or "eat me" signal, which we hypothesize makes Actimab-A potentially synergistic with magrolimab and other anti-CD47 antibodies. The Actimab-A and magrolimab combination showed a significant increase in survival compared to Actimab-A alone in a disseminated AML animal tumor model. We intend to continue to study preclinically this combination with the goal of advancing to human clinical trials.

In January 2022, we announced a research collaboration with EpicentRx that will evaluate Actimab-A in combination with EpicentRx's RRx-001in AML. EpicentRx's RRx-001, currently under investigation in a Phase 3 trial for Small Cell Lung Cancer and in other oncology and non-oncology indications, is a versatile next generation small molecule immunotherapeutic that targets the CD47-SIRPα axis and the NLRP3 inflammasome to alter the tumor microenvironment and optimize immune response. This collaboration will explore the mechanistic synergy of RRx-001's CD47–SIRPα downregulation with Actinium's targeted radiotherapy calreticulin upregulation to increase the immune detection and destruction of cancer cells. Preclinical experiments have begun exploring this combination in AML models. We intend to leverage our experience with CD47 targeting agents such as magrolimab in this collaboration. Based on Actimab-A and RRx-001 both being clinical-stage assets, we believe there is a potentially faster pathway to clinical trials with this novel combination, particularly if the preclinical safety and efficacy profile are in line with what was observed with Actimab-A and magrolimab.

Antibody Warhead Enabling Technology Platform

Our proprietary AWE technology platform is supported by intellectual property, know-how and trade secrets that cover the generation, development, methods of use and manufacture of targeted radiotherapies and certain of their components. Our AWE technology patent portfolio presently includes 45 patent families comprised of over 195 issued patents and pending patent applications, of which 12 are issued and 39 are pending in the United States, and 145 are issued or pending internationally. The effective lives of the issued patents in our portfolio, or patents that may issue from the pending applications in our portfolio, ranges from expirations between 2024 and 2043. Our technology enables the direct labeling, or conjugation and labeling, of a biomolecular targeting agent to a radionuclide warhead and its development and use as a therapeutic regimen for the treatment of diseases such as cancer. Our AWE intellectual property covers various methods of use in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations. We have particular expertise in utilizing the alpha emitting isotope Ac-225 including clinical experience in treating approximately 150 patients with our alpha-emitter-based therapies, "gold standard" linker technology and 5 issued patents in the United States and 49 patents internationally related to the manufacturing or Ac-225 in a cyclotron, which we believe has the potential to produce higher quantities of Ac-225 than currently utilized methods.

Our research is focused on applying our AWE technology platform to the development of radiation conjugates and to execute on research collaborations. Our R&D efforts employ a multidisciplinary approach leveraging our team's knowledge and experience in cancer cell biology, radiochemistry, radiation sciences, immunology and oncology drug development. We intend to focus on generating targeted radiotherapies using our existing intellectual property, evaluating assets for in-licensing to complement our existing clinical pipeline and securing collaborations and partnerships with biopharmaceutical companies. By adding research and development capabilities to our clinical development and clinical supply chain capabilities, we seek to enable the rapid translation of radiotherapies.

Our AWE technology platform is being utilized in our ongoing research collaboration with Astellas to arm select targeting agents owned by Astellas with the alpha-emitting radioisotope Ac-225 for the development of theranostics for solid tumor indications, which combine the ability of radioisotopes to be used for both diagnostic and therapeutic purposes.

We also utilized AWE to create a HER2-targeting radiotherapy using the antibody Trastuzumab with either Ac-225 or Lu-177 radioisotopes to study in combination with magrolimab for solid tumors. Anti-CD47 monotherapies, such as magrolimab, have not shown meaningful responses in clinical studies in solid tumors. We hypothesized that radiation directed at HER2 expressing cells would upregulate cell surface calreticulin, a pro-phagocytic "eat me" signal, that when combined with an anti-CD47 blockade therapy would enhance antitumor activity. Data from this combination was presented at the Annual Meeting of the Society for Immunotherapy for Cancer in November 2021. In vitro studies showed that immunogenicity, determined by binding to HER2 expressing cells, remained intact after radiolabeling Trastuzumab with Ac-225 or Lu-177. In multiple cells lines radiolabeled Trastuzumab increased cell surface calreticulin and the combination with magrolimab increased phagocytosis. The combination of the Ac-225 or Lu-117 Trastuzumab with magrolimab slowed tumor growth in animal models of solid tumors compared to either the radiolabeled Trastuzumab or magrolimab as single agents. We are continuing to evaluate this combination in additional tumor models, and we intend to continue to study this combination with the goal of advancing to human clinical trials.

We are also collaborating with AVEO Oncology ("AVEO") to develop a targeted radiotherapy against ErbB3, also known as HER3, with the Ac-225 isotope for solid tumor indications. HER3 is overexpressed in several solid tumor indications with high unmet needs, including colorectal, gastric, head and neck, breast, ovarian, melanoma, prostate and bladder cancers with HER3 agents under development demonstrating activity in preclinical and clinical studies. To our knowledge, this is the first HER3 targeting radiotherapy in development. AVEO is developing high affinity antibodies including HER3 targeting AV-203, which has demonstrated preclinical activity across a number of solid tumor indications and was studied in a Phase 1 open-label trial in patients with advanced solid tumors where it was found to be safe and generally well tolerated. In April 2022, we presented data at the AACR Annual Meeting showing potent tumor cell cytotoxicity, enhanced antitumor effects and significantly improved survival with an Ac-225 radiolabeled HER3 antibody compared to a naked HER3 antibody in a preclinical NSCLC model. We believe these preliminary results support our collaboration with AVEO and given that AV-203 has clinical safety data, a potentially accelerated regulatory pathway to clinical studies with an Ac-225 HER3 targeted radiotherapy.

Recent Developments

Impact of COVID–19 Pandemic

The global health crisis caused by the novel coronavirus COVID-19 pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, the Omicron variants of COVID-19, including subvariants BA.4 and BA.5, which appear to be the most transmissible variants to date, have spread globally. The full impact of the Omicron variants, or any subsequent variants, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Omicron variants and the response by governmental bodies and regulators. Given the ongoing and dynamic nature of the circumstances, it is difficult to predict the impact of the COVID-19 pandemic on our business.

Many countries around the world have continued to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Accordingly, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented hybrid working for our office-based staff, while our research staff has been actively working in our laboratory throughout the pandemic and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development, preclinical research or manufacturing of our drug candidates. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of the coronavirus, which may be more contagious and deadly than prior strains. Therefore, the COVID-19 pandemic may continue to affect our operation, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effect on our operations.

A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We believe our earlier stage CD33 clinical trials will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the continuation and/or resurgence of the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us, which may result in delays or hinder our ability to collect data from our clinical trials.

Additionally, COVID-19 may result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

To date, COVID-19 has not had a financial impact on our company. We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. Although we expect that vaccinations for COVID-19 will continue to improve conditions, the ultimate impact from COVID-19 on our business operations and financial results during 2022 will depend on, among other things, the ultimate severity and scope of the pandemic, including the new variants of the virus, the pace at which governmental and private travel restrictions and public concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, if at all, and whether, and the speed with which the economy recovers. We are not able to fully quantify the impact that these factors will have on our financial results during 2022 and beyond.

Results of Operations – Three Months Ended June 30, 2022 Compared to Three Months Ended June 30, 2021

The following table sets forth, for the periods indicated, data derived from our statements of operations:

(in thousands)	For the Three Months Ended June 30, 2022	2021
Revenue:		
Revenue	$ -	$ -
Other revenue	45	266
Total revenue	45	266
Operating expenses:		
Research and development, net of reimbursements	4,662	3,631
General and administrative	3,233	1,710
Total operating expenses	7,895	5,341
Other income:		
Interest income – net	83	54
Total other income	83	54
Net loss	$ (7,767)	$ (5,021)

Revenue

We recorded no commercial revenue for the three months ended June 30, 2022 and June 30, 2021.

Other revenue

We determined that certain collaborations with a third-party are within the scope of Topic ASC 606, *Revenue Recognition from Contracts with Customers,* or ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. While the third party has the option to terminate the agreement at the conclusion of any module, we identified a single performance obligation to provide research services within each module for which we receive monetary consideration. Other revenue recognized during the three months ended June 30, 2022 and June 30, 2021 was $45 thousand and $0.3 million respectively.

Research and development, net of reimbursements

Research and development expenses of $4.7 million for the three months ended June 30, 2022 increased $1.1 million from $3.6 million for the three months ended June 30, 2021. Higher expenses related to increased compensation of $0.5 million, resulting from increased compensation expenses and higher expenses due to an increase in the number of employees and increased research activities at our laboratory space.

General and administrative

General and administrative expenses of $3.2 million for the three months ended June 30, 2022 increased $1.5 million from $1.7 million for the three months ended June 30, 2021. The increase was primarily attributable to increased compensation of $0.8 million, higher professional fees and consulting fees including recruitment costs, and higher legal fees.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the three months ended June 30, 2022 of $83 thousand increased from $54 thousand for the three months ended June 30, 2021 due to a higher average balance.

Net loss

Net loss of $7.8 million for the three months ended June 30, 2022 increased by $2.8 million from $5.0 million for the three months ended June 30, 2021, due to the increases in research and development expenses and general and administrative expenses.

Results of Operations – Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

The following table sets forth, for the periods indicated, data derived from our statements of operations:

	For the Six Months Ended June 30,	
(in thousands)	**2022**	**2021**
Revenue:		
Revenue	$ -	$ -
Other revenue	985	888
Total revenue	985	888
Operating expenses:		
Research and development, net of reimbursements	9,031	7,907
General and administrative	4,968	3,428
Total operating expenses	13,999	11,335
Other income:		
Interest income – net	118	106
Total other income	118	106
Net loss	$ (12,896)	$ (10,341)

Revenue

We recorded no commercial revenue for the six months ended June 30, 2022 and June 30, 2021.

Other revenue

We determined that certain collaborations with a third-party are within the scope of ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. While the third party has the option to terminate the agreement at the conclusion of any module, we identified a single performance obligation to provide research services within each module for which we receive monetary consideration. Other revenue recognized during the six months ended June 30, 2022 and June 30, 2021 was $0.9 million and $0.9 million respectively.

The National Institutes of Health awarded us a Small Business Technology Transfer cost reimbursable grant to support a clinical collaboration with Memorial Sloan Kettering Cancer Center, or MSK, to study Iomab-ACT for targeted conditioning to achieve lymphodepletion prior to administration of a CD19-targeted CAR T-cell therapy developed at MSK. We recognized other revenue during the six months ended June 30, 2022 of $0.1 million.

Research and development, net of reimbursements

Research and development expenses of $9.0 million for the six months ended June 30, 2022 increased $1.1 million from $7.9 million for the six months ended June 30, 2021. The increase was due to higher expenses related to our research activities at our laboratory space and government grant program and increased compensation of $0.5 million.

General and administrative

General and administrative expenses of $5.0 million for the six months ended June 30, 2022 increased $1.6 million from $3.4 million for the six months ended June 30, 2021. The increase was primarily attributable to increased compensation of $0.8 million, higher professional fees and consulting fees including recruitment costs, and higher legal fees.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the six months ended June 30, 2022 of $0.1 million was unchanged from the prior-year period.

Net loss

Net loss of $12.9 million for the six months ended June 30, 2022 increased by $2.6 million from $10.3 million for the six months ended June 30, 2021, due to the increases in research and development expenses and general and administrative expenses.

Liquidity and Capital Resources

Historically, we have financed our operations primarily through sales of shares of our stock. The following tables sets forth selected cash flow information for the periods indicated:

	For the Six Months Ended June 30,	
(in thousands)	**2022**	**2021**
Cash provided by/used in operating activities	$ 22,137	$ (10,226)
Cash used in investing activities	(277)	(65)
Cash provided by financing activities	16,641	28,644
Net change in cash, cash equivalents and restricted cash	$ 38,501	$ 18,353

Net cash provided by operating activities for the six months ended June 30, 2022 of $22.1 million increased by $32.3 million from a use of funds of $10.2 million in the prior-year period. This increase was due to the receipt of the $35.0 million up-front payment from Immedica.

Net cash used in investing activities of $0.3 million for the six months ended June 30, 2022 and $0.1 million for the prior-year period are primarily due to the acquisition of equipment for our laboratory.

Net cash provided by financing activities for the six months ended June 30, 2022 of $16.6 million and for the six months ended June 30, 2021 of $28.6 million was primarily from the sale of shares of our common stock.

We entered into a lease for corporate office space effective June 1, 2022 and paid a security deposit to the landlord. The lease has a term of 5 years 2 months, with an expiration date of July 30, 2027, and a current annual rate of $0.6 million. We are also responsible for certain other costs, such as insurance, taxes, utilities and maintenance. In July, 2022 a certificate of deposit was provided as collateral for a letter of credit and the security deposit was returned.

In August 2020 we entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of our common stock. Shares of common stock are offered pursuant to our shelf registration statement on Form S-3 filed with the SEC on August 7, 2020. As of December 31, 2021, we had sold 6.7 million shares of common stock, resulting in gross proceeds of $59.1 million and net proceeds of $57.0 million. For the six months ended June 30, 2022, we sold 2.7 million shares of common stock, resulting in gross proceeds of $17.2 million and net proceeds of $16.7 million. For the six months ended June 30, 2021, we sold 3.5 million shares of common stock, resulting in gross proceeds of $29.6 million and net proceeds of $28.7 million.

On June 28, 2022, we entered into an Amendment and Restated Capital on Demand™ Sales Agreement, or the A&R Sales Agreement, with JonesTrading and B. Riley Securities, Inc., or B. Riley Securities. The A&R Sales Agreement modifies the original Capital on Demand™ Sales Agreement to include B. Riley Securities as an additional sales agent thereunder.

As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are described in detail in the notes to our consolidated financial statements appearing in our Annual Report filed on Form 10-K for the year ended December 31, 2021.

Revenue Recognition

We recognize revenue in accordance with ASC 606. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue as we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess whether the promised goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. In determining whether goods or services are distinct, we evaluate certain criteria, including whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (capable of being distinct) and (ii) the good or service is separately identifiable from other goods or services in the contract (distinct in the context of the contract).

ASC 606 requires us to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in the new revenue standard as the price at which an entity would sell a promised good or service separately to a customer. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Collaborative Arrangements

We follow the accounting guidance for collaboration agreements, which requires that certain transactions between us and collaborators be recorded in our consolidated statements of operations and comprehensive loss on either a gross basis or net basis, depending on the characteristics of the collaborative relationship, and requires enhanced disclosure of collaborative relationships. We evaluate our collaboration agreements for proper classification in our consolidated statements of operations and comprehensive loss based on the nature of the underlying activity. When we conclude that we have a customer relationship with one of our collaborators, we follow the guidance of ASC 606.

License Revenue

We entered into a product licensing agreement whereby we allowed a third party to commercialize a certain product in specified territories using our trademarks. The terms of this arrangement includes payment to us for a combination of one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; and royalties on net sales of licensed products. We use judgment to determine whether milestones or other variable consideration should be included in the transaction price.

Upfront license fees: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time.

Development, regulatory or commercial milestone payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and sales-based or commercial events, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until regulatory approval is received. At the end of each subsequent reporting period, we will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of license revenues during the period of adjustment.

Sales-based milestone payments and royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, we will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements or when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with any variable consideration is subsequently resolved. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional.

Research and Development Costs

Research and development costs are expensed as incurred. These costs include the costs of manufacturing drug product, the costs of clinical trials, costs of employees and associated overhead, and depreciation and amortization costs related to facilities and equipment. Research and development reimbursements are recorded by us as a reduction of research and development costs.

Share-Based Payments

We estimate the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. We account for forfeitures of stock options as they occur.

Accounting Standards Recently Adopted

In May 2021, FASB issued ASU 2021-04, *Earnings Per Share (topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718) and Derivatives and Hedging – Contracts in an Entity's Own Equity (Subtopic 815-40) – Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, which provides guidance of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU are effective January 1, 2022, including interim periods. We adopted this standard effective January 1, 2022 and the standard did not have a material effect on our financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance*, which provides guidance on disclosure requirements to entities other than not-for-profit entities about transaction with a government that are accounted for by applying a grant or contribution accounting model by analogy. ASU 2021-10 requires an entity to make annual disclosures related to (1) the nature of the transactions and the related accounting policy used to account for the government transactions, (2) quantification and disclosure of amounts related to the government transactions included in balance sheet and income statement financial statement line items, and (3) significant terms and conditions of the government transactions, including commitments and contingencies. The amendments of ASU 2021-10 are effective January 1, 2022, including interim periods. We adopted this standard effective January 1, 2022 and the standard did not have a material impact on our financial statements.

Accounting Standards Recently Issued

In October 2021, FASB issued ASU 2021-08, *Business Combinations (Topic 805), Account for Contract Assets and Contract Liabilities from Contracts with Customers*, which provides guidance on accounting for contract assets and contract liabilities acquired in a business combination in accordance ASC 606. To achieve this, an acquirer may assess how the acquiree applied ASC 606 to determine what to record for the acquired revenue contracts. Generally, this should result in an acquirer recognizing and measuring the acquired contract assets and contract liabilities consistent with how they were recognized and measured in the acquiree's financial statements. The amendments of ASU 2021-08 are effective January 1, 2023, including interim periods. Early adoption is permitted, including adoption in an interim period. We will evaluate the impact of ASU 2021-08 on any future business combinations that we may enter in the future.

Subsequent Events

Since June 30, 2022, we have sold 0.3 million shares of common stock under our A&R Sales Agreement, resulting in net proceeds of $1.4 million.

On August 2, 2022, warrants to purchase an aggregate of 0.6 million shares of common stock expired. These warrants were issued on August 2, 2017, when we completed an underwritten offering of 0.7 million shares of our common stock and warrants to purchase an aggregate of 0.6 million shares of our common stock at a price of $22.50 per share and related warrant. The warrants were exercisable for a period of 5 years at an exercise price of $31.50 per share. As of August 12, 2022, we have 1.4 million warrants outstanding.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are not currently exposed to significant market risk related to changes in interest rates. As of June 30, 2022, our cash equivalents consisted primarily of short-term money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the cash equivalents in our portfolio and the low risk profile of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value of our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the six months ended June 30, 2022 and 2021.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of June 30, 2022, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that, as of June 30, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. There were no changes in our system of internal controls over financial reporting during the period covered by this report that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our Annual Report filed on Form 10-K for the year ended December 31, 2021. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our company. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Summary of Risk Factors

We are providing the following summary of the risk factors contained in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- We are a clinical-stage company and have generated no revenue from commercial sales to date;
- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future;
- If we fail to obtain additional financing, we will be unable to continue or complete our product development and you will likely lose your entire investment;
- We are highly dependent on the success of Iomab-B and the SIERRA trial and we may not be able to complete the necessary clinical development or our development efforts may not result in the data necessary to receive regulatory approval;
- Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic;
- We have not demonstrated that any of our products are safe and effective for any indication and will continue to expend substantial time and resources on clinical development before any of our current or future product candidates will be eligible for FDA approval, if ever;
- Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization;
- Preliminary, Interim, and "top-line" 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.;

- Healthcare legislative reform measures intended to increase pressure to reduce prices of pharmaceutical products paid for by Medicare or, otherwise, affect the federal regulation of the U.S. healthcare system could have a material adverse effect our business, future revenue, if any, and results of operations;

- We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates;

- We currently depend on a single third-party manufacturer to produce our pre-clinical and clinical trial drug supplies. Any disruption in the operations of our current third-party manufacturer, or other third-party manufacturers we may engage in the future, could adversely affect our business and results of operations;

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

- Our patent position is highly uncertain and involves complex legal and factual questions.

- The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials;

- We are highly dependent on our key personnel, and the demand for talent in the biotechnology industry is highly competitive; if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement or execute our business strategy;

- Certain provisions of our Certificate of Incorporation and Bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest; and

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

Risks Related to Our Business

We are a clinical-stage company and have generated no revenue from commercial sales to date.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are not profitable and have incurred losses in each period since our inception. As of June 30, 2022, and December 31, 2021, we had an accumulated deficit of $268.6 million and $255.7 million, respectively. We reported a net loss of $12.9 million and $10.3 million for the six months ended June 30, 2022, and 2021, respectively. We expect to continue to operate at a net loss as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, which would have an adverse effect on our business prospects, financial condition and results of operation.

If we fail to obtain additional financing, we will be unable to continue or complete our product development and you will likely lose your entire investment.

In August 2020, we entered into the Capital on Demand™ Sales Agreement with JonesTrading, pursuant to which we may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of our common stock. Shares of common stock are offered pursuant to our shelf registration statement filed with the SEC on August 7, 2020. As of December 31, 2021, we had sold 6.7 million shares of common stock, resulting in gross proceeds of $59.1 million and net proceeds of $57.0 million. For the six months ended June 30, 2022, we sold 2.7 million shares of common stock, resulting in gross proceeds of $17.2 million and net proceeds of $16.7 million.

On June 28, 2022, we entered into an Amendment and Restated Capital on Demand™ Sales Agreement, or the A&R Sales Agreement, with JonesTrading and B. Riley Securities, Inc., or B. Riley Securities. The A&R Sales Agreement modifies the Original Capital on Demand™ Sales Agreement to include B. Riley Securities as an additional sales agent thereunder.

As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred cancer treatment modalities. However, we may not be able to secure funding when we need it or on favorable terms or indeed on any terms. In addition, from time to time, we may not be able to secure enough capital in a timely enough manner which may cause the generation of a going-concern opinion from our auditors which can and may impair our stock market valuation and also our ability to finance on favorable terms or indeed on any terms.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise have retained for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of funding we will need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our preclinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

We have limited access to the capital markets and even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.

We have limited access to the capital markets to raise funds. The capital markets have been unpredictable in the recent past for radioisotope and other oncology companies and unprofitable companies such as ours. In addition, it is generally difficult for development-stage companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our technology licenses, results of operations, financial condition and our continued viability will be materially adversely affected.

We are highly dependent on the success of Iomab-B and the SIERRA trial and we may not be able to complete the necessary clinical development or our development efforts may not result in the data necessary to receive regulatory approval.

We have completed patient enrollment in the pivotal Phase 3 SIERRA trial (Study of Iomab-B in Elderly Relapsed or Refractory AML), a 153-patient multi-center randomized trial that will compare outcomes of patients who receive Iomab-B and a BMT to those patients receiving physician's choice of salvage chemotherapy, defined as conventional care, as no standard of care exists for this patient population. The SIERRA trial may be unsuccessful and fail to demonstrate a safety and efficacy profile that is necessary to receive favorable regulatory approval. Even if Iomab-B receives favorable regulatory approval, we may not be successful in securing adequate reimbursement or establishing successful commercial operations. Any or all of these factors could have a material adverse impact on our business and ability to continue operations.

We may be unable to establish sales, marketing and commercial supply capabilities.

We do not currently have, nor have we ever had, commercial sales and marketing capabilities. If any of our product candidates become approved, we would have to build and establish these capabilities in order to commercialize our approved product candidates. The process of establishing commercial capabilities will be expensive and time consuming. Even if we are successful in building sales and marketing capabilities, we may not be successful in commercializing any of our product candidates. Any delays in commercialization or failure to successfully commercialize any product candidate may have material adverse impacts on our business and ability to continue operations.

Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic.

The global health crisis caused by the novel coronavirus COVID-19 pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, the Omicron variants of COVID-19, including subvariants BA.4 and BA.5, which appear to be the most transmissible variants to date, have spread globally. The full impact of the Omicron variant, or any subsequent variant, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against the Omicron variant and the response by governmental bodies and regulators. Given the ongoing and dynamic nature of the circumstances, it is difficult to predict the impact of the COVID-19 pandemic on our business.

Many countries around the world have continued to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Accordingly, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented remote working and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development of our drug candidates. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of the coronavirus, which may be more contagious and deadly than prior strains. Therefore, the COVID-19 pandemic may continue to affect our operation, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effect on our operations.

A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We believe our earlier stage CD33 clinical trials will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the continuation and/or resurgence of the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us, which may result in delays or hinder our ability to collect data from our clinical trials.

Additionally, COVID-19 may result in delays in receiving approvals from domestic and foreign regulatory authorities, delays in necessary interactions with Institutional Review Boards ("IRBs"), domestic and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. However, the ultimate impact from COVID-19 on our business operations and financial results during 2022 will depend on, among other things, the ultimate severity and scope of the pandemic, including the new variants of the virus, the pace at which governmental and private travel restrictions and public concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, if at all, and whether, and the speed with which the economy recovers. We are not able to fully quantify the impact that these factors will have on our financial results during 2022 and beyond.

Our business is subject to cybersecurity risks.

Our operations are increasingly dependent on information technologies and services. Threats to information technology systems associated with cybersecurity risks and cyber incidents or attacks continue to grow, and include, among other things, storms and natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error, and complications encountered as existing systems are maintained, repaired, replaced, or upgraded. Risks associated with these threats include, among other things:

- theft or misappropriation of funds;
- loss, corruption, or misappropriation of intellectual property, or other proprietary, confidential or personally identifiable information (including supplier, clinical data or employee data);
- disruption or impairment of our and our business operations and safety procedures;
- damage to our reputation with our potential partners, patients and the market;
- exposure to litigation; and
- increased costs to prevent, respond to or mitigate cybersecurity events.

Although we utilize various procedures and controls to mitigate our exposure to such risk, cybersecurity attacks and other cyber events are evolving and unpredictable. Moreover, we have no control over the information technology systems of third parties conducting our clinical trials, our suppliers, and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period time.

We have cybersecurity insurance coverage in the event we become subject to various cybersecurity attacks, however, we cannot ensure that it will be sufficient to cover any particular losses we may experience as a result of such cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulation

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of seeking regulatory approval to market an antibody radiation-conjugate product is expensive and time-consuming, and, notwithstanding the effort and expense incurred, approval is never guaranteed. If we are not successful in obtaining timely approval of our products from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. In particular, the FDA permits commercial distribution of a new antibody radiation-conjugate product only after a BLA for the product has received FDA approval. The BLA process is costly, lengthy and inherently uncertain. Any BLA filed by us will have to be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, chemistry, manufacturing and controls ("CMC") and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The approval process in the United States and in other countries could result in unexpected and significant costs for us and consume management's time and other resources. The FDA and other foreign regulatory agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain approval to market our products in the United States or in other countries, the approval could be revoked, or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA or other regulatory authorities will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be materially adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications that we request. The Company's products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

We have not demonstrated that any of our products are safe and effective for any indication and will continue to expend substantial time and resources on clinical development before any of our current or future product candidates will be eligible for FDA approval, if ever.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to development of our existing and contemplated biological product candidates. Accordingly, our business currently depends heavily on the successful development, FDA approval, and commercialization of such candidates, which may never receive FDA approval or be successfully commercialized even if FDA approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of our biological product candidates are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, as applicable. We are currently not permitted to market any of our current or future product candidates in the United States until we receive FDA approval (of each) via the BLA process. To date, we have two product candidates in clinical development and have not-yet submitted a BLA for any of our candidates and, for many such candidates, do not expect to be in a position to do so for the foreseeable future, as there are numerous developmental steps that must be completed before we can prepare and submit a BLA.

In the United States, the FDA regulates pharmaceutical and biological product candidates under the FDCA and the Public Health Service Act ("PHSA"), as well as their respective implementing regulations. Such products and product candidates are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies in accordance with FDA's good laboratory practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug ("IND"), which must become effective before human clinical trials in the United States may begin;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's IND regulations, GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of preclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMPs and assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or denial, of the BLA.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, for those that have already commenced under an active IND, that issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all. Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Our product candidates are in the earliest stages of clinical development and, therefore, a long way from BLA submission. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for our product candidates or whether any such BLA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also lengthy and requires substantial time and effort.

In December 2015, the FDA cleared our IND filing for Iomab-B and we have completed patient enrollment of a randomized, controlled, pivotal Phase 3 clinical trial under such IND to study Iomab-B in patients 55 years of age or older with relapsed or refractory AML. Assuming the Phase 3 trial meets its endpoints and there are no unexpected issues or delays, it is expected to form the basis for a BLA for Iomab-B for use in preparing and conditioning AML patients for a BMT. Additionally, there are physician IND trials at the FHCRC that have been conducted or are currently ongoing at FHCRC with Iomab-B (for other target indications) and the apamistamab antibody (formerly known as BC8) we licensed. And, we have multiple Phase 1 and Phase 2 clinical trials ongoing and others that we have planned but not-yet commenced, for our other drug candidates under our own sponsorship and multiple investigator-initiated trials ongoing. Except for Iomab-B (for patients with AML), we expect that the clinical trials we need to conduct to be in a position to submit BLAs for our product candidates currently in-development will take, at least, several years to complete. Moreover, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Also, the results of early preclinical and clinical testing may not be predictive of the results of subsequent clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. And, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have, nonetheless, failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. Any failure or substantial delay in our product development plans may have a material adverse effect on our business.

We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the collection or analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates and potentially cause our product candidates to fail to receive regulatory approval:

- conditions imposed on us by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from IRBs or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;
- inadequate supply, delays in distribution, deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;
- unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;
- a finding that the trial participants are being exposed to unacceptable health risks;
- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial;
- delays in obtaining regulatory agency authorization for the conduct of our clinical trials;
- delays by us or third parties in the collection or analysis of data from our clinical trials; or
- delays due to COVID-19 or a similar global health pandemic.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks including but not limited to unacceptable or suboptimal factors related to toxicity, clinical efficacy, imbalances in safety and efficacy profiles or for other reasons.

Further, individuals involved with our clinical trials may serve as consultants to us from time to time and receive stock options or cash compensation in connection with such services. If these relationships and any related compensation to the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized. The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our product candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB (Data Safety Monitoring Board)/DMC (Data Monitoring Committee), overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- varying interpretation of data by the FDA or similar foreign regulatory authorities;
- failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Modifications to our product candidates may require federal approvals.

The BLA application is the vehicle through which the company may formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. Once a particular product candidate receives FDA approval, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals, including additional IND and BLA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions.

Conducting clinical trials and obtaining approvals is a time-consuming process, and delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business prospects, financial condition and results of operation.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans, and we may fail to obtain regulatory approval of our product candidates.

In June 2012, we acquired rights to apamistamab, a clinical stage anti-CD45 monoclonal antibody with safety and efficacy data in more than 300 patients in need of a BMT. Iomab-B is our product candidate that links I-131 to apamistamab that is being studied in the pivotal Phase 3 SIERRA trial. Product candidates utilizing apamistamab would require BLA approval before they can be marketed in the United States. We are also evaluating Iomab-ACT, which uses a lower dose I-131 for lymphodepletion prior to CAR-T or adoptive cell therapy. We are currently evaluating clinical trials that would use our construct for lymphodepletion. Our lintuzumab-Ac-225 product candidate is also being studied in several Phase 1 trials under our sponsorship and investigator-initiated trials in patients with r/r AML. Product candidates utilizing the lintuzumab antibody would require BLA approval before they can be marketed in the United States. We are in the early stages of evaluating other product candidates consisting of conjugates of Ac-225 with human or humanized antibodies for pre-clinical and clinical development in other types of cancer. The FDA may not approve these products for the indications that are necessary or desirable for successful commercialization. The FDA may fail to approve any BLA we submit for new product candidates or for new intended uses or indications for approved products or future product candidates. Failure to obtain FDA approval for our products in the proposed indications would have a material adverse effect on our business prospects, financial condition and results of operations.

Clinical trials necessary to support approval of our product candidates are time-consuming and expensive.

Initiating and completing clinical trials necessary to support FDA approval of a BLA for Iomab-B, CD33 program candidates, and other product candidates, is a time-consuming and expensive process, and the outcome is inherently uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. We worked with the FDA to develop the SIERRA clinical trial to test the safety and efficacy of Iomab-B in patients with relapsed or refractory AML who are age 55 and above prior to a BMT. This trial is designed to support a BLA filing for marketing approval by the FDA, pending results from the trial. In addition to clinical data, a BLA filing encompasses preclinical, CMC, labeling and other information. Even if the clinical data from the SIERRA trial is positive, there can be no assurances that the BLA filing we produce will meet all of the FDA's requirements or that they will not request additional information or studies, which may delay the FDA's review or we may not be able to produce. We have also worked with the FDA to develop a regulatory pathway for lintuzumab-Ac-225 in patients with high-risk MDS that consists of a dose-confirming Phase 1 trial that can be followed by a randomized, controlled pivotal trial that could support a BLA filing. To date, we have not initiated this clinical trial and we may never elect or be able to do so. There can be no assurance that the data generated during the trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of a BLA. Even if the data from this trial are favorable, the data may not be predictive of the results of any future clinical trials.

Preliminary, Interim, and "top-line" 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, and top-line data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as more patient data become available or following a more comprehensive review of the data related to the particular study or trial. For example, at the ASH annual meeting in December 2021 and TCT annual meeting in April 2022, we presented safety and feasibility data available at the time of data submission from 100% patient enrollment from the SIERRA trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Our clinical trials may be open label studies and certain of our clinical development and or operations staff may review interim or preliminary safety or efficacy data during routine data collection, cleaning and analysis from time to time. Interim 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. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line, interim or preliminary data we previously published. As a result, top-line, interim and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between 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.

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

If the interim, top-line or preliminary data that we report differ from final 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 fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for Iomab-B, Actimab-A, or any other product candidate for which we might seek approval, have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate's profile.

The intellectual property related to antibodies we have licensed has expired or likely expired.

The key patents related to the humanized antibody, lintuzumab, which we use in our CD33 program product candidates have expired. It is generally possible that others may be eventually able to use an antibody with the same sequence, and we will then need to rely on additional patent protection covering alpha particle drug products comprising Ac-225. Our final drug construct, Actimab-A, consists of the lintuzumab antibody labeled with the isotope Ac-225. We currently own issued and pending patents relating to methods of manufacturing Actimab-A, methods of treatment using Actimab-A and production of the Ac-225 isotope. In addition, we possess trade secrets and know how related to the manufacturing and use of isotopes. Any competing product based on the lintuzumab antibody is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but such development by others is nevertheless a possibility that could negatively impact our business in the future. We own 4 issued U.S. patents, 1 issued European patent (validated as a national patent in several countries) and 1 issued Japanese patent that relate to the composition of our Iomab-B product candidate. Several patent applications relating to Iomab-B are also pending in the U.S. and internationally. We have and may continue to file patents related to Iomab-B that can provide barriers to entry but there is no certainty that these patents will be granted or such granting thereof will adequately prevent others from seeking to replicate and use the apamistamab antibody or the construct. We have pending patents related to radioimmunoconjugate composition, formulation administration, and methods of use in solid or liquid cancers. This subject matter includes composition, administration, and methods of treatment for our product candidates Actimab-A and Iomab-B. Any competing product based on the antibody used in Iomab-B is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but such development by others is nevertheless a possibility that could negatively impact our business in the future.

Our CD33 program clinical trials are testing the same drug construct.

Our CD33 program is comprised of several clinical trials including investigator-initiated trials in AML that are studying the same drug construct consisting of lintuzumab-Ac-225. Negative results from any of these trials could negatively impact our ability to enroll or complete our other trials studying lintzumab-Ac-225. Additionally, negative outcomes including safety concerns, may result in the FDA discontinuing other trials utilizing lintuzumab-Ac-225.

We may be unable to obtain a sufficient supply of isotopes to support clinical development or at commercial scale.

Iodine-131 is a key component of our Iomab-B drug candidate. We currently source medical grade I-131 from three suppliers including two leading global manufacturers. Currently, there is sufficient supply of I-131 to advance our ongoing SIERRA clinical trial, support additional trials we may undertake utilizing I-131 and for commercialization of Iomab-B. We continually evaluate I-131 manufacturers and suppliers and intend to have multiple qualified suppliers prior to the commercial launch of Iomab-B. While we consider I-131 to be commoditized and obtainable through several suppliers, there can be no guarantee that we will be able to secure I-131 or obtain I-131 on terms that are acceptable to us.

Actinium-225 is a key component of our CD33 ARC program, AWE platform and other drug candidates that we might consider for development with the Ac-225 payload. There are adequate quantities of Ac-225 available today to meet our current needs via our present supplier, the Department of Energy ("DOE"). The current Ac-225 currently supplied to Actinium's clinical trials from the DOE is derived from the natural decay of thorium-229 from so-called 'thorium-cows' and is able to produce sufficient quantities that are several multiples of the amount of Ac-225 we require to supply our clinical programs through to early commercialization phase. The DOE is also producing Ac-225 from a recently developed alternative route for Ac-225 production via a linear accelerator that is currently being evaluated by Actinium. Initial preclinical and modelling results have indicated that the linear accelerator sourced Ac-225 does not impact labelling efficiency and expected distribution. In accordance with representations made by the DOE, the capacity of Ac-225 from this route is expected to be sufficient to supply all of Actinium's pipeline and commercial Ac-225 needs and support new program expansion by not just Actinium but also other companies that are developing Ac-225 based products. Additional routes of Ac-225 production are being pursued by the DOE including the generation of new thorium cows and production via a cyclotron. The cyclotron production method for Ac-225 production leverages Actinium's proprietary technology and know-how and presents an additional path towards production of high-quality Ac-225 that would be able to satisfy commercial needs. In addition, we are aware of at least six other government and non-government entities globally including the U.S., Canada, Russia, Belgium, France and Japan that have, or expect to have ability to supply Ac-225 or equipment for its production within the timeframes relevant to the potential first commercial approval of our Ac-225 ARC.

Our contract for supply of Ac-225 from the DOE must be renewed annually and our current contract extends through the end of 2022. While we expect this contract will continue to be renewed at the end of its term as it has since 2009, there can be no assurance that the DOE will renew the contract or change its policies that allow for the sale of isotope to us. Failure to acquire sufficient quantities of medical grade Ac-225 would make it impossible to effectively complete clinical trials and to commercialize any Ac-225 based drug candidates that we may develop and would materially harm our business.

Our ability to conduct clinical trials to advance our ARC drug candidates is dependent on our ability to obtain the radioisotopes I-131, Ac-225 and other isotopes we may choose to utilize in the future. Currently, we are dependent on third party manufacturers and suppliers for our isotopes. These suppliers may not perform their contracted services or may breach or terminate their agreements with us. Our suppliers are subject to regulations and standards that are overseen by regulatory and government agencies and we have no control over our suppliers' compliance to these standards. Failure to comply with regulations and standards may result in their inability to supply isotopes and could result in delays in our clinical trials, which could have a negative impact on our business. We have developed intellectual property, know-how and trade secrets related to the manufacturing process of Ac-225. While we have manufactured medical grade Ac-225 of a purity compared to the cyclotron sourced material in the past, this activity was terminated due to operating cost reasons and we currently do not have experience in manufacturing medical grade Ac-225 and may not obtain the resources necessary to establish our own manufacturing capabilities in future. Our inability to build out and establish our own manufacturing facilities would require us to continue to rely on third party suppliers as we currently do. However, based on our current third-party suppliers and potential future suppliers of Ac-225 we expect to have adequate isotope supply to support our current ongoing clinical trials, current AWE program activities and commercialization should our drug candidates receive approval.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and expertise;
- competing clinical trials for similar or alternate therapeutic treatments;
- clinician's and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, refractory patients, which several of our trials are enrolling, participating in clinical trials are seriously and often terminally ill and therefore may not complete the clinical trial due to reasons including comorbid conditions or occurrence of adverse medical events related or unrelated to the investigational products, or death. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment will result in increased costs or affect the timing of our planned trials, which could adversely affect our ability to advance the development of our product candidates.

FDA may take actions that would prolong, delay, suspend, or terminate clinical trials of our product candidates, which may delay or prevent us from commercializing our product candidates on a timely basis.

There can be no assurance that the data generated in our clinical trials will be acceptable to FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to FDA. Certain modifications to a clinical trial protocol made during the course of the clinical trial have to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, FDA could take the position that some or all of the data generated by the clinical trial is not usable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying approval of a product candidate. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any submissions with the FDA, delay the approval and commercialization of our product candidates or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of our Iomab-B clinical trials would adversely affect our business and prospects and could cause us to cease operations.

We have obtained orphan drug designation from FDA for two of our current product candidates and intend to pursue such designation for other candidates and indications in the future, but we may be unable to obtain such designations or to maintain the benefits associated with any orphan drug designations we have received or may receive in the future.

We have received orphan drug designation for Iomab-B and lintuzumab-CD33 ARC for treatment of AML in both the United States and the EU. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making available a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Similarly, the EMA grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU.

Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. In addition, if a product candidate receives the first FDA approval for the indication for which it has orphan designation, such product is entitled, upon approval, to seven years of orphan-drug exclusivity, during which the FDA may not approve any other application to market the same drug for the same indication, unless a subsequently approved product is clinically superior to orphan drug or where the manufacturer is unable to assure sufficient product quantity in the applicable patient population. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even if we obtain (or have obtained) orphan drug designation for certain product candidates, we may not be the first to obtain marketing approval for such candidates for the applicable indications due to the uncertainties inherent in the development of novel biologic products. And, an orphan drug candidate may not receive orphan-drug exclusivity upon approval if such candidate is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Finally, even if we successfully obtain orphan-drug exclusivity for an orphan drug candidate upon approval, such exclusivity may not effectively protect the product from competition because (i) different drugs with different active moieties can be approved for the same condition; and (ii) the FDA or EMA can also subsequently approve a subsequent product with the same active moiety and for the same indication as the orphan drug if the later-approved drug if deemed clinically superior to the orphan drug.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

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

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates which could limit our sales of our product candidates, if approved.

The commercial success of our product candidates in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved cancer therapies is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of a BLA for that product and may not be granted until many months after BLA approval. In order to obtain coverage and reimbursement for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

Healthcare legislative reform measures intended to increase pressure to reduce prices of pharmaceutical products paid for by Medicare or, otherwise, affect the federal regulation of the U.S. healthcare system could have a material adverse effect our business, future revenue, if any, and results of operations.

In the United States, there have been a number of legislative and regulatory initiatives focused on containing the cost of healthcare. The Affordable Care Act, for example, substantially changed the way healthcare is financed by both governmental and private insurers. The Affordable Care Act contains a number of provisions that could impact our business and operations, primarily, once we obtain FDA approval to commercialize one of our product candidates in the United States, if ever, and may also affect our operations in ways we cannot currently predict. Affordable Care Act provisions that may affect our business include, among others, those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, fees and increased discount and rebate obligations, transparency and reporting requirements, and fraud and abuse enforcement. Such changes may impact existing government healthcare programs, industry competition, formulary composition, and may result in the development of new programs, including Medicare payment for performance initiatives, health technology assessments, and improvements to the physician quality reporting system and feedback program.

There have been significant ongoing judicial, administrative, executive, and legislative initiatives to modify, limit, replace, or repeal the Affordable Care Act. For example, former President Trump issued several Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress considered legislation that would repeal or replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation the Affordable Care Act have been passed. For example, the Tax Cuts and Jobs Act of 2017 eliminated the Affordable Care Act provision requiring individuals to purchase and maintain health coverage, or the "individual mandate," by reducing the associated penalty to zero, beginning in 2019. In December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the Affordable Care Act is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the Affordable Care Act. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the Affordable Care Act's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the Affordable Care Act will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The adoption or implementation of new or amended legislation at the federal or state level could affect our ability to obtain regulatory approval for any of our vaccine candidates and the commercial viability of our future approved products, if any. We cannot predict the ultimate nature, timing, or effect of any changes to the Affordable Care Act or other federal and state reform efforts, and there is no assurance that such efforts will not adversely affect our future business and financial results.

In addition to the Affordable Care Act, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Pharmaceutical product prices have been the focus of increased scrutiny by the government, including certain state attorneys general, members of Congress and the United States Department of Justice. State or federal healthcare reform measures or other social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in November 2021, President Biden announced the "Prescription Drug Pricing Plan" as part of the Build Back Better Act (H.R. 5376) passed by the House of Representatives on November 19, 2021, which aims to lower prescription drug pricing by, among other things, allowing Medicare to negotiate prices for certain high-cost prescription drugs covered under Medicare Part D and Part B after the drugs have been on the market for a certain number of years and imposing tax penalties on drug manufacturers that refuse to negotiate pricing with Medicare or increase drug prices "faster than inflation." If enacted, this bill could have a substantial impact on our business, particularly once we have commercially available products on the U.S. market, if ever. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the potential success of our vaccine candidates.

Our relationships with customers, health care professionals and third-party payors may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings.

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors 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 conduct research, market, sell and distribute any products for which we obtain marketing approval. Federal and state healthcare laws and regulations that may affect our operations, directly or indirectly, include the following, among others:

- the federal Anti-Kickback Statute, which prohibits persons and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal false claims laws, including civil whistleblower or qui tam actions under the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of the covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the federal Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value provided to physicians and any ownership and investment interests held by physicians or their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- analogous state laws and regulations, including (among others) state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the United States federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Efforts to comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, imprisonment, additional reporting obligations and oversight (if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws), and the curtailment or restructuring of our operations, any of which could diminish our future profits or earnings. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Third-party payors may not adequately reimburse customers for any of our products that we may commercialize or promote and may impose coverage restrictions or limitations such as prior authorizations and step edits that affect their use.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Obtaining reimbursement approval for any product candidate for which we obtain marketing approval from any government or other third-party payor is a time-consuming and costly process. There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Even when a payor determines that a product that we may commercialize or promote is eligible for reimbursement under its criteria, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA, or may impose restrictions, such as prior authorization requirements, or may simply deny coverage altogether. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Furthermore, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain and maintain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

Risks Related to Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct our clinical trials for our product candidates and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as GCPs (good clinical practices), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If we or any of our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice, or ("cGMP") regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If our consultants, contract research organizations and other similar entities with which we are working do not successfully carry out their contractual duties, meet expected deadlines, or comply with applicable regulations, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, we may not be able to enter into arrangements with alternative third-party contractors or to do so on commercially reasonable terms, which may result in a delay of our planned clinical trials and delayed development of our product candidates.

In addition, our third-party contractors are not our employees, and except for remedies available to us under our agreements with such third-party contractors, we cannot control whether or not they devote sufficient time and resources to our programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates on a timely basis, if at all, and our business, operating results and prospects would be adversely affected.

The antibodies we use in our targeted radiotherapy product candidates may be subject to generic competition.

We are not aware of any existing or pending regulations or legislation that pertains to generic radiopharmaceutical products such as antibody radiation-conjugate product candidates. Our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. Even if a biosimilar gets approved for one of the antibodies that we use, the final constructs of our drug candidates consist of an antibody, radioisotope and in some cases a linker. Therefore, we do not believe that the final drug product of our candidates can be subject to competition from a biosimilar as outlined in BPCIA.

Our product candidates may never achieve market acceptance.

Iomab-B, CD33 program candidates and future product candidates that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

We believe that oncologists and other physicians will not widely adopt a product candidate unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that the use of that product candidate provides an effective alternative to other means of treating specific cancers. Patient studies or clinical experience may indicate that treatment with our product candidates does not provide patients with sufficient benefits in extension of life or quality of life. We believe that recommendations and support for the use of each product candidate from influential physicians will be essential for widespread market acceptance. Our product candidates are still in the development stage and it is premature to attempt to gain support from physicians at this time. We can provide no assurance that such support will ever be obtained. If our product candidates do not receive such support from these physicians and from long-term data, physicians may not use or continue to use, and hospitals may not purchase or continue to purchase, them.

Failure of Iomab-B, CD33 program candidates or any of our other product candidates to significantly penetrate current or new markets would negatively impact our business financial condition and results of operations.

We may be subject to claims that our third-party service providers, consultants or current or former employees have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ 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 confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We currently depend on single third-party manufacturers to produce our pre-clinical and clinical trial drug supplies. Any disruption in the operations of our current third-party manufacturers, or other third-party manufacturers we may engage in the future, could adversely affect our business and results of operations.

We do not currently operate manufacturing facilities for pre-clinical or clinical production of any of our product candidates. We rely on third-party manufacturers to supply, store, and distribute pre-clinical and clinical supply of the components of our drug product candidates including monoclonal antibodies, linkers and radioisotopes, as well as the final construct which comprises our drug product candidates. We expect to continue to depend on third-party manufacturers for the foreseeable future. Any performance failure on the part of our existing or future manufacturers could delay clinical development, cause us to suspend or terminate development or delay or prohibit regulatory approval of our product candidates or commercialization of any approved products. Further avenues of disruption to our clinical or eventual commercial supply may also occur due to the sale, acquisition, business reprioritization, bankruptcy or other unforeseen circumstances that might occur at any of our suppliers or contract manufacturing partners including an inability to come to terms on renewal of existing contracts or new contracts.

We currently rely on single manufacturers to manufacture our pre-clinical and clinical trial drug supplies. With a view to maintaining business continuity we are evaluating alternatives and second and even third sources of supply or manufacturing for our core suppliers and manufacturing partners, however there can be no assurances that we will be able to identify such suppliers or partners and assuming we did, that we would be able to enter into contracts that are on favorable terms or on terms that will enable sufficient supply to ensure business continuity and support our growth plans.

Our product candidates require precise, high-quality manufacturing. Failure by our current contract manufacturer or other third-party manufacturers we may engage in the future to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs and other applicable government regulations and corresponding foreign standards; we do not have control over third-party manufacturers' compliance with these regulations and standards.

We may elect to build or purchase a manufacturing facility or facilities in the future to operate for the purposes of manufacturing our own products. We have never built, owned or operated a manufacturing facility. There can be no assurances that we will be able to successfully accomplish this and in doing so we may experience delays, cost overruns, or other problems that could seriously hurt our business. Even if we successfully build or purchase a manufacturing facility, we may not realize the expected benefits of these efforts.

We depend on vendors with specialized operations, equipment and know-how to manufacture the respective components of our drug candidates. We have entered into manufacturing and supply agreements with these third-parties, and in some instances, we have agreed that such vendor be the exclusive manufacturer and supplier. If any of the third-parties we depend on encounter difficulties in their operations, fail to comply with required regulations or breach their contractual obligations it may be difficult, or we may be unable to identify suitable alternative third-party manufacturers. While we identify and evaluate third-party manufacturers from time to time, even if we do identify suitable alternative third-parties, we may fail to reach agreement on contractual terms, it may be prohibitively expensive and there can be no assurance that we can successfully complete technology transfer and development work necessary or complete the necessary work in a timely manner. Any of which could prevent us from commencing manufacturing with third-parties which could cause delays or suspension of our clinical trials and pre-clinical work that may have a negative impact on our business.

Furthermore, these third-party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shutdowns, employee strikes, or any other unforeseeable acts that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third-party manufacturers to consistently supply quality product when required would have a material adverse effect on our ability to develop or commercialize our products. We have faced delays and risks associated with reliance on key third party manufacturers in the past and may be faced with such delays and risks in the future. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including delays in clinical trials.

If we are successful in obtaining marketing approval from the FDA and/or other regulatory agencies for any of our product candidates, we anticipate continued reliance on third-party manufacturers.

To date, our product candidates have been manufactured in small quantities for preclinical and clinical testing by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party specialized manufacturers to produce commercial quantities of approved products. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. Scale-up for commercial product may require financial commitment or investment by us, which we may not have sufficient capital for or may elect not to undertake. If third party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply, which in turn could have a material adverse effect on our business.

In addition, the facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is averse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that may receive regulatory approval. In order to commercialize any product candidates after approval, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. In particular, we have and expect to continue to partner with third parties to commercialize Iomab-B outside the United States. In April 2022, we entered into a licensing agreement with Immedica, in which Immedica acquired the product rights for commercialization of Iomab-B for certain territories outside the U.S. If we are unable to enter into or maintain such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We face significant competition from other biotechnology and pharmaceutical companies.

Our product candidates face, and will continue to face, intense competition from large pharmaceutical and biotechnology companies, as well as academic and research institutions. We compete in an industry that is characterized by (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our product candidates and technologies and may develop and commercialize additional products and technologies that will compete with our product candidates and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to (i) provide broader services and product lines, (ii) make greater investments in research and development, or R&D, and (iii) carry on broader R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking preclinical and clinical testing of product candidates, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our product candidates receives marketing approval, as greater numbers of patients use a product following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;

- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may elect, or we may be required, to recall or withdraw product from the market;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

Risks Related to Our Intellectual Property

We depend upon securing and protecting critical intellectual property.

We are dependent on obtaining and maintaining patents, trade secrets, copyright and trademark protection of our technologies in the United States and other jurisdictions, as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. The degree of future protection of our proprietary rights is uncertain for product candidates that are currently in the early stages of development because we cannot predict which of these product candidates will ultimately reach the commercial market or whether the commercial versions of these product candidates will incorporate proprietary technologies.

Our patent position is highly uncertain and involves complex legal and factual questions.

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced under our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid, and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, such preferred position would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents for medical use, manufacture, conjugation and labeling of Ac-225, the antibodies that we license from third parties, or subsequent related filings, would adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and we do not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

In addition to infringement or other intellectual property claims against us, we may become a party to other patent litigation or proceedings before regulatory agencies, including post-grant review, inter parties review, interference or re-examination proceedings filed with the U.S. Patent and Trademark Office (or similar proceedings before corresponding tribunals in other jurisdictions) that challenge our patent rights or the patent rights of our licensors. The costs and efforts of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings can be substantial and the outcome can be uncertain. An adverse determination in these proceedings could weaken or invalidate the patent claims that cover our technology, which adverse determination could harm our business significantly and dissuade companies from collaborating with us or permit third parties to directly compete with the same technology.

Our ability to protect and enforce our patents does not guarantee that we will secure the right to commercialize our patents.

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using its invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention where other permissions may be required for commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.

We rely on trade secrets that we seek to protect through numerous measures, including non-compete and confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. Any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others. We have learned that a former employee violated the non-compete provision of their employment agreement by working for a direct competitor. This employee, who had access to materials containing proprietary information and trade secrets, may have been solicited, and until recently, pursuant to actions taken by Actinium, was employed by a direct competitor. We intend to fully investigate this matter and, if appropriate, pursue litigation against all parties that may be involved to protect our confidential information and trade secrets.

Risks Related to Our Operations

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are potentially able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a public company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioactive isotopes. We are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use and disposal of these materials and some waste products. We cannot completely eliminate the risk of contamination or injury from these materials and we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.

Although we do not have any international operations at this time, we intend to seek market clearances in foreign markets that we believe will generate significant opportunities. However, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business. If any member of our current senior management terminates his employment with us and we are unable to find a suitable replacement quickly, the departure could have a material adverse effect on our business. An overall tightening and increasingly competitive labor market has been observed in the U.S. employment market generally, especially in response to the COVID-19 pandemic. Specific to the biotechnology industry in which we operate, there is significant demand and competition for highly specialized talent that we require. A sustained labor shortage or increased turnover rates within our employee base, caused by the COVID-19 pandemic, as a result of general macroeconomic factors, or due to dynamics within our industry, could lead to increased costs, such as increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently conduct our clinical development, R&D, business development and potential regulatory and commercial activities. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, have unintended negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation, caused by the COVID-19 pandemic, general macroeconomic factors or as a result of biotechnology industry dynamics could have a material adverse impact on our operations, results of operations, liquidity or cash flows.

Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel. This activity is likely to create additional demands on the time and attention of our senior management personnel as they identify, hire, and train external and internal candidates to fill the sizable number of positions required to execute our business plans including submit a BLA and build a commercial organization. The market for talent in our industry is very competitive. Many of the other biopharmaceutical companies we compete against for qualified personnel have greater financial and other resources, more favorable risk profiles and a longer operating history in the biopharmaceutical industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates than what we have to offer.

It is particularly difficult to recruit and hire new employees during the COVID-19 pandemic as conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or meet or continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and workforce could adversely affect our ability to operate, grow and manage our business.

Managing our growth as we expand operations may strain our resources.

We expect to need to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our product candidates as well as potential commercial operations, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could materially harm our business, financial condition or results of operations.

We may expand our business through the acquisition of rights to new product candidates that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of product candidates, antibodies or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We can make no assurances that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds, or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current stockholder's ownership interest in the Company.

Risks Related to Ownership of Our Common Stock

The sale of securities by us in any equity or debt financing could result in dilution to our existing stockholders and have a material adverse effect on our earnings.

We have financed our operations primarily through sales of stock and warrants. It is likely that during the next twelve months we will seek to raise additional capital through the sales of stock and warrants in order to expand our level of operations to continue our research and development efforts.

Any sale of common stock by us in a future offering could result in dilution to our existing stockholders as a direct result of our issuance of additional shares of our capital stock. In addition, our business strategy may include expansion through internal growth or by establishing strategic relationships with targeted customers and vendors. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could dilute our stockholders' stock ownership. We may also assume additional debt and incur impairment losses related to goodwill and other tangible assets if we acquire another company and this could negatively impact our earnings and results of operations.

Our common stock is subject to price volatility which could lead to losses by stockholders and potential costly security litigation.

The trading volume of our common stock has been and may continue to be extremely limited and sporadic. We expect the market price of our common stock to fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

The trading price of our common stock may be highly volatile and could fluctuate in response to factors such as:

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- the timing of IND and/or BLA approval, the completion and/or results of our clinical trials;
- regulatory actions regarding our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. Moreover, the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent months. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and our resources, which could harm our business and financial condition.

We do not intend to pay dividends on our common stock, so any returns will be determined by the value of our common stock.

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, it is expected that earnings, if any, generated from our operations will be used to finance the growth of our business, and that no dividends will be paid to holders of our common stock. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value.

Certain provisions of our Certificate of Incorporation and Bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- provide that the authorized number of directors may be changed by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes; and
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice.

In addition, we are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public 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 mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the Securities and Exchange Commission and furnishing audited reports to stockholders are substantial. In addition, we will incur substantial expenses in connection with the preparation of registration statements and related documents with respect any offerings of our common stock.

Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, including with respect to more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We complied with Section 404 at December 31, 2021 and 2020 and while our testing did not reveal any material weaknesses in our internal controls, any material weaknesses in our internal controls in the future would be required us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, NYSE American or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common stock and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Multiple securities and industry analysts currently cover us. If one or more of the analysts downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which could cause the price of our common stock and trading volume to decline.

Our amended and restated bylaws, as amended, designate the U.S. federal district courts as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

Our amended and restated bylaws, as amended, provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. In addition, our amended and restated bylaws, as amended, state that any person purchasing or otherwise acquiring any interest in our security shall be deemed to have notice of and to have consented to such provision. Such choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits, if successful, might benefit our stockholders. Stockholders who do bring a claim in the federal district courts of the United States of America could face additional litigation costs in pursuing any such claim.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Copies of the following documents are included as exhibits to this report pursuant to Item 601 of Regulation S-K.

Exhibit No.	Description
3.1	Certificate of Incorporation of Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed with the SEC on April 17, 2013).
3.2	Certificate of Amendment to Certificate of Incorporation, as amended, filed January 7, 2014 (incorporated by reference to Exhibit 3.5 to Form S-1 filed on January 31, 2014).
3.3	Certificate of Amendment to Certificate of Incorporation, as amended, filed February 3, 2014. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 7, 2014).
3.4	Certificate of Amendment to Certificate of Incorporation, as amended, filed on February 26, 2015 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 4, 2015).
3.5	Certificate of Amendment to Certificate of Incorporation, as amended, filed on February 26, 2018 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 26, 2018).
3.6	Certificate of Amendment to Certificate of Incorporation, as amended, filed on March 6, 2019 (incorporated by reference to Exhibit 3.7 to Form 10-K filed on March 15, 2019).
3.7	Certificate of Amendment to Certificate of Incorporation, as amended, filed on June 16, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 16, 2020).
3.8	Certificate of Amendment to Certificate of Incorporation, as amended, filed on August 10, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on August 14, 2020).
3.9	Amended and Restated Bylaws, dated August 8, 2018 (incorporated by reference to Exhibit 3.1 to Form 10-Q filed on August 9, 2018).
3.10	Amendment to Amended and Restated Bylaws, dated May 7, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 5, 2020).
10.1+†*	Exclusive License and Supply Agreement, dated April 7, 2022, between Immedica Pharma AB and Actinium Pharmaceuticals, Inc.
10.2*	Sublease Agreement, dated April 28, 2022, between ABN AMRO HOLDINGS USA LLC and Actinium Pharmaceuticals, Inc.
31.1*	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2**	Certification of the Principal Financial and Accounting Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS *	Inline XBRL Instance Document
101.SCH *	Inline XBRL Taxonomy Schema Document
101.CAL *	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF *	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB *	Inline XBRL Taxonomy Label Linkbase Document
101.PRE *	Inline XBRL Taxonomy Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.
# Indicates a management contract or compensatory plan or arrangement.
\+ Certain of the schedules (and similar attachments) to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5) of Regulation S-K under the Securities Act of 1933, as amended, because they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the Exhibit or the disclosure document. The registrant hereby agrees to furnish a copy of all omitted schedules (or similar attachments) to the SEC upon its request.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K under the Securities Act of 1933, as amended, because they are both (i) not material and (ii) the type that the registrant treats as private or confidential. A copy of the omitted portions will be furnished to the SEC upon its 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.

ACTINIUM PHARMACEUTICALS, INC.

Date: August 12, 2022

By: */s/ Sandesh Seth*
Sandesh Seth
Chairman and Chief Executive Officer
(Duly Authorized Officer and
Principal Executive Officer)

By: */s/ Steve O'Loughlin*
Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer and
Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION MARKED BY [*] HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE OR CONFIDENTIAL.

EXCLUSIVE LICENSE AND SUPPLY AGREEMENT

THIS EXCLUSIVE LICENSE AND SUPPLY AGREEMENT **("Agreement")** is made effective as of the 7th day of April, 2022 (the **"Effective Date"),** by and between Immedica Pharma AB, a corporation organized and existing under the laws of Sweden with registration number, 556835-6322 and offices at Norrtullsgatan 15, SE 113 29 Stockholm, Sweden **("IMMEDICA")** and Actinium Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware and with offices at 275 Madison Avenue, 7th Floor, New York, NY 10016, U.S.A. **("LICENSOR").** IMMEDICA and LICENSOR may, from time-to-time, be individually referred to as a **"Party"** and collectively referred to as the **"Parties".**

RECITALS

WHEREAS, LICENSOR Controls the Licensed Technology (hereinafter defined); and

WHEREAS, IMMEDICA wishes to obtain, and LICENSOR wishes to grant, certain licenses under the Licensed Technology on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS

1.1. **"Additional Clinical Studies"** has the meaning given in Section 4.2.1.

1.2. **"Additional Indication Study"** has the meaning given in Section 4.2.2.

1.3. **"Additional Product"** has the meaning given in Section 2.4.

1.4. **"Affiliate"** means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, **"control"** shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

1.5. **"Applicable Laws"** means all applicable laws, statutes, rules, regulations and guidelines, including, without limitation, all applicable standards or guidelines promulgated by any Regulatory Authority, including to the extent applicable, GLP, GCP and GMP.

1.6. **"AML"** means Acute Myeloid Lukemia.

1.7. **"Business Day"** means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, NY, U.S.A. or Sweden are authorized or required by law to remain closed.

1.8. **"Calendar Quarter"** means each period of three (3) consecutive months ending on March 31, June 30, September 30, or December 31.

1.9. **"Calendar Year"** means the period of twelve (12) consecutive months corresponding to the calendar year commencing on the first day of January and ending on the last day of December, and each successive twelve (12) month period thereafter.

1.10. **"Claims"** means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees).

1.11. **"Clinical Studies"** means any study in which human subjects are dosed or treated with a drug or biological product, whether approved or investigational and including paediatric studies and investigator sponsored studies.

1.12. **"Commercialize" or "Commercialization"** means any and all activities related to pre-marketing, launching, marketing, promotion (including advertising and detailing), serialization, bidding and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing, having imported, exporting, having exported, distributing, having distributed, supplying for named patient use, providing customer service and support, conducting medical affairs, conducting post-marketing safety surveillance and reporting of or otherwise commercializing or exploiting the Product. **"Commercializing"** has the correlative meaning.

1.13. **"Commercially Reasonable Efforts"** means that level of efforts that a similarly situated biopharmaceutical company would normally use, in the exercise of its prudent scientific and business judgment, for the development and/or commercialization of a comparable pharmaceutical product for a similar patient population at a similar stage of its development or commercialization, taking into account all relevant scientific, commercial, business and other factors, including issues of safety and efficacy, expected and approved product labeling, expected and actual cost and time to develop, expected and actual profitability, the nature and extent of expected and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected likelihood of marketing approval, and the expected and actual amounts of marketing and promotional expenditures required. Commercially Reasonable Efforts shall be determined on a country-by-country basis and it is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular country will change over time.

1.14. **"Control" or "Controlled"** means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant the applicable access to, or a license or a sublicense of or under, such Intellectual Property Rights to the other Party without breaching the terms of any agreement with a Third Party existing as of the Effective Date, or at such later time as such Party first acquires rights to such subject matter.

1.15. **"Cover"** means, with respect to a compound, product, technology, process or method, that in the absence of ownership of or a license granted under a Valid Claim, the Manufacture, use, offer for sale, sale or importation of such product or the practice of such technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue as then being prosecuted). **"Covered by"** has the correlative meaning.

1.16. **"Develop" or "Development"** means to conduct any and all non-clinical and clinical research and development activities, including non-clinical development, toxicology, pharmacology, statistical analysis, Clinical Studies (including pre- and post-approval studies), regulatory affairs, and regulatory activities pertaining to designing and carrying out clinical studies and all activities necessary to obtain Regulatory Approval.

1.17. **"EMA"** means the European Medicines Agency or any successor agency thereto.

1.18. **"Executive Officers"** means with respect to each Party, the chief executive officer of such Party or another senior officer designated by such chief executive officer.

1.19. **"Existing Agreements"** means the [*].

1.20. **"Facility" or "Facilities"** shall mean the following GMP manufacturing facilities utilized by LICENSOR or its Third Party contract manufacturers in the manufacture of the Product: [*].

1.21. **"FDA"** shall mean the United States Food and Drug Administration, or any successor agency thereto.

1.22. **"FDCA"** shall mean the U.S. Federal Food, Drug and Cosmetic Act.

1.23. **"Fees"** means collectively, the upfront payment, all Milestone Payments, and Royalties.

1.24. **"Field"** means all uses in humans including the treatment of AML, bone marrow transplant conditioning, non-myeloablative conditioning, and lymphodepletion.

1.25. **"First Commercial Sale"** means, on a country-by-country basis, the first sale for use, or consumption, by the general public of the Product following receipt of all Regulatory Approvals for such Product in such country in the Territory.

1.26. **"Force Majeure Event"** has the meaning set out in Section 19.5.

1.27. **"Good Clinical Practice" or "GCP"** means the current standards for clinical studies for pharmaceuticals, as set forth in the ICH guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the European Union, to the extent such standards are not less stringent than United States Good Clinical Practice.

1.28. **"Good Laboratory Practice" or "GLP"** means the current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Union, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.29. **"Good Manufacturing Practice" or "GMP"** shall mean current good manufacturing practice and standards as provided for (and as amended from time to time) in the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 CPR §§ 210, 211, 601 and 610) and the most recent approved edition of European Commission Directives applicable to the production of pharmaceutical products, as interpreted by the ICH Harmonized Tripartite Guideline, and related regulations or guidance documents subsequently established by any applicable governmental or regulatory authority in the United States or European Union.

1.30. **"Housemarks"** shall mean the trade name Actinium Pharmaceuticals, Inc.

1.31. **"Iomab-B"** means the pharmaceutical product known by that name comprising a CD45 directed monoclonal antibody known as apamistamab linked to Iodine-131.

1.32. **"Intellectual Property Rights"** means all trade secrets, Know-How, copyrights, patents and other patent rights, trademarks, moral rights, service marks, industrial designs, mask works, integrated circuit topographies, confidential information, trade names, goodwill and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction, whether registered or unregistered, and including rights in any application for any of the foregoing.

1.33. **"Know-How"** means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including manufacturing procedures, test procedures, and purification and isolation techniques in written, electronic or any other form, and all other discoveries, developments, inventions (whether or not patented or patentable), and tangible embodiments of any of the foregoing, in each case that is not generally known to the public.

1.34. **"Licensed Know-How"** means all Know-How Controlled by LICENSOR or any of its Affiliates as of the Effective Date or during the term of this Agreement that is necessary or useful for seeking and obtaining Regulatory Approval for the Product in the Field in the Territory or for the Development or Commercialization of the Product in the Field in the Territory.

1.35. **"Licensed Patents"** means: (a) the patents and patent applications listed in Schedule A, (b) all Patent Rights that claim priority to the patents or patent applications described in subsection (a), and (c) any other Patent Rights Controlled by the LICENSOR or any of its Affiliates as of the Effective Date or during the term of this Agreement that Cover the Development or Commercialization of a Product or that claim Licensed Know-How (including in each case all related Patent Rights as described in clauses (a)-(e) of Section 1.43 below).

1.36. **"Licensed Technology"** means collectively, the Licensed Patents and Licensed Know-How.

1.37. **"Manufacture" and "Manufacturing"** means all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling and shipping of any Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control. **"Manufactured"** has the correlative meaning.

1.38. **"Manufacturing Agreements"** means those agreements entered into by or on behalf of the LICENSOR or its Affiliates which relate to the manufacture of the Product or any part thereof, which is to be, or which has been, supplied to IMMEDICA under this Agreement, including the associated drug substance and drug product manufacturing agreements. At the Effective Date, the Manufacturing Agreements include (a) the Manufacturing Services Agreement, dated [*], between LICENSOR and [*], (b) the Agreement for Services, dated [*], between LICENSOR and [*] and (c) the Radiochemical Supply Agreement, dated [*], between LICENSOR and [*].

1.39. **"Materials"** shall mean, excipients and solvents and other chemicals and other raw materials (including the CD45 directed monoclonal antibody known as apamistamab) and components, packaging and shipping materials (including vials) and other materials and supplies reasonably necessary to perform the Services.

1.40. **"Milestone"** means each milestone as set forth in Schedule B.

1.41. **"Milestone Payment"** has the meaning set out in Section 6.1.2.

1.42. **"Net Sales"** means the sales revenues received by or on behalf ofIMMEDICA and its Affiliates and Sublicensees for sales of the Product to Third Parties, less the following deductions if and to the extent they are included in the gross invoiced sales price of the Product or otherwise incurred by IMMEDICA and its Affiliates or Sublicensees with respect to the sale of the Product: (a) rebates, quantity and cash discounts, and other usual and customary discounts to customers, (b) Taxes (but excluding, for the avoidance of doubt, income taxes paid or payable by IMMEDICA, its Affiliates and Sublicensees with respect to such sales) and any other duties paid, absorbed or allowed which are directly related to the sale of the Product, (c) credits, allowances, discounts and rebates, and chargebacks for spoiled, damaged, out-dated, recalled, rejected or returned Product, (d) actual freight and insurance costs incurred in transporting the Product to customers, (e) discounts or rebates or other payments required by Applicable Law, including any governmental special medical assistance programs, and (f) customs duties, surcharges and other governmental charges and rebates incurred in connection with the exportation or importation of the Product . Subsections (a) through (f) shall be collectively referred to as **"Deductions".**

The following principles shall apply in the calculation of Net Sales:

1.42.1. The provision of the Product at no charge for the purpose of conducting pre-clinical or clinical research, or as donations or the like or as "treatment IND sales", "named patient sales", "compassionate use sales", or pursuant to any expanded access programs, or any equivalent sales, in each case shall not be deemed to be included in Net Sales.

1.42.2. Transfers of Product between IMMEDICA and its Affiliates and/or Sublicensees shall not be treated as Net Sales for the purposes of this Agreement.

1.42.3. Unless otherwise specified herein, Net Sales shall be calculated in accordance with IMMEDICA's, or its Affiliate's or Sublicensees's applicable accounting practices generally and consistently applied.

1.43 **"Other Product"** has the meaning given in Section 2.4.

1.44 **"Patent Rights"** means with respect to any patents or patent applications, any and all (a) patents issuing from such patent applications, (b) substitutions, divisionals, renewals, continuations or continuations-in-part (only to the extent of claims that are entitled to the priority date of the parent application); (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confinnation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (d) other patents or patent applications claiming and entitled to claim priority to (i) such patents and patent applications and any patent or patent application specified in (a), (b) or (c), or (ii) any patent or patent application from which such patents and patent applications or a patent or patent application specified in (a), (b) or (c) claims and is entitled to claim priority; (d) all rights of priority attendant to such patents and patent applications and any of the patents and patent applications listed in (a) through (d); and (e) in each case of such patents and patent applications and of the patents and patent applications described in (a) through (d), including all counterparts and foreign equivalents thereof filed in any country, territory or jurisdiction in the world.

1.45 **"Person"** means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.46 **"Phase III Clinical Trial"** means the phase III clinical study of the Product titled "Iomab-B (131-I apamistamab)" having ClinicalTrials.gov identifier NCT02665065 having the official title of A Multicenter, Pivotal Phase 3 Study of **Iomab-B** Prior to Allogeneic Hematopoietic Cell Transplant Versus Conventional Care in Older Subjects With Active, Relapsed or Refractory Acute Myeloid Leukemia (AML).

1.47 **"Product"** means any pharmaceutical product containing, incorporating or comprising **1311-** apamistamab (including the product currently known as Iomab-B both dosimetric and therapeutics doses and the product currently known as Iomab-Act), irrespective of salt form or excipients, in any formulation, mode of administration, presentation or dosage form.

1.48 **"Product Trademark"** any trademark used exclusively in relation to the Products in the Territory.

1.49 **"Protocol"** means sponsor protocol number 8, as such protocol may be amended from time to time by LICENSOR after discussion at the JSC.

1.50 **"Quality Agreement"** has the meaning set forth in Section 7.3.

1.51 **"Regulatory Approval"** means, with respect to the Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Regulatory Authority to market and sell the Product in such country or jurisdiction and including any orphan drug designations or similar rights.

1.52 **"Regulatory Authority"** means the EMA or any governmental agency or authority responsible for granting Regulatory Approvals for the Product in any country or jurisdiction in the Territory.

1.53 **"Regulatory Filings"** means, with respect to the Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any submission to a regulatory advisory board, any marketing authorization application, any application for orphan drug designation, and any supplement or amendment thereto. As used herein, "Regulatory Filings" also includes all correspondence with any Regulatory Authority (and their agents) regarding Product, including all submissions, meeting minutes, reports and other items submitted to a Regulatory Authority by or under authority of a Party, its Affiliates or its Sublicensees with respect to a Product, or the Development, Manufacture or Commercialization thereof.

1.54 **"Royalties"** has the meaning set out in Section 6.1.3.

1.55 **"Services"** shall mean the commercial Manufacture of Product to be performed by the LICENSOR under this Agreement.

1.56 **"Specifications"** shall mean the specifications for Manufacturing the Product ready for use, including without limitation all regulatory, manufacturing, quality control and quality assurance procedures, processes, practices, standards instructions and other attributes for the Product as set forth on Schedule C, as such specifications may be amended by the Parties due to new data with approval from Regulatory Authority or due to other regulatory requirements, from time to time.

1.57 **"Sublicense"** means a written agreement appointing a Sublicensee.

1.58 **"Sublicensee"** means any Third Party to which IMMEDICA has delegated substantially all of its rights and obligations under this Agreement with respect to any jurisdiction(s) in the Territory, including all of the following: (i) the exclusive (even as to IMMEDICA) right to purchase Product from LICENSOR (directly or indirectly via IMMEDICA) for sale or use in such jurisdiction(s), (ii) the exclusive (even as to IMMEDICA) right to seek or hold Regulatory Approval (other than where such Regulatory Approval is to be held on behalf of IMMEDICA) for the Product in such jurisdiction(s); (iii) the exclusive right (even as to IMMEDICA) to set the price of the Product in such jurisdiction(s); and (iv) the obligation to Commercialize the Product in such jurisdiction(s).

1.59 **"Supply Failure"** means a failure by LICENSOR to supply at least [*]% of the Product ordered by IMMEDICA under this Agreement in two Calendar Quarters in any Calendar Year.

1.60 **"Target"** means [*].

1.61 **"Taxes"** has the meaning set forth in Section 6.3.1.

1.62 **"Territory"** means the current members states of the European Economic Area (together with any country that becomes a member of the European Economic Area), Algeria, Andorra, Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya. Monaco, Morocco, Oman, Palestine, Qatar, San Marino, Saudi Arabia, Switzerland, Syria, Tunisia, Turkey, the United Arab Emirates, the United Kingdom, the Vatican City and Yemen. For the avoidance of doubt, if a country ceases to be a member state of the European Economic Area then, notwithstanding such cessation, such country shall remain part of the Territory

1.63 **"Third Party"** means any Person other than a Party or an Affiliate of a Party

1.64 **"Valid Claim"** means either: (a) a claim of an issued and unexpired Patent Right, which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (b) a claim of a pending application for a Patent Right, which claim: (i) is within [*] from its earliest priority date and was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application and (ii) has not been admitted to be invalid or unenforceable through reissue, reexamination, or disclaimer and which is not subject to an interference claim.

2. LICENSE GRANT

2.1. **License Grant.**

2.1.1. **Licensed Technology.** Subject to the terms and conditions of this Agreement, LICENSOR hereby grants to IMMEDICA an exclusive, royalty-bearing right and license with the right to grant Sublicenses, as provided in Section 2.2, under the Licensed Technology to Develop and Commercialize the Product in the Field within the Territory. Such license shall not include a license to Manufacture the Product unless IMMEDICA takes over responsibility for Manufacture in accordance with Section 7.8.5 provided that IMMEDICA shall be entitled to carry out QP release of and to import the Product. IMMEDICA shall not itself or through or with any Third Party, conduct or facilitate any research or Development directly related to the Product outside of the Territory without LICENSOR's prior written consent.

2.1.2. **Trademarks.** LICENSOR grants to IMMEDICA an exclusive right and license to use all (i) Product Trademarks owned or Controlled by LICENSOR or its Affiliates and the Housemarks to the extent that the Housemarks are applied by LICENSOR to the Product or its packaging, in each case in connection with the Commercialization of the Product in the Field within the Territory. All marks, whether registered or unregistered, used in connection with the Products must be approved, in writing, by the LICENSOR prior to use in the Territory which approval will not be unreasonably withheld, conditioned or delayed.

2.2. **Sublicense Rights.** IMMEDICA may grant a Sublicense of the rights granted to it by LICENSOR under this Agreement only with LICENSOR's prior written consent, and subject to the following requirements:

2.2.1. Any such Sublicenses shall be subject to and consistent with the terms and conditions of this Agreement, including, without limitation, with respect to confidentiality, record keeping obligations and audit rights;

2.2.2. Unless otherwise agreed by the LICENSOR and IMMEDICA, IMMEDICA shall act as the representative of its Sublicensees for purposes of exercising rights under Section 7 of this Agreement;

2.2.3. IMMEDICA shall remain responsible for the payment to LICENSOR of all Milestone Payments and Royalties payable with respect to Net Sales of Products made by such Sublicensees;

2.2.4. IMMEDICA shall remain liable for the actions and omissions of each Sublicensee; and

2.2.5. IMMEDICA shall furnish to LICENSOR an accurate and complete copy of each Sublicense agreement with a Third Party and each amendment thereto prior to execution, provided that any such copy may be redacted to remove any commercially sensitive or financial terms, or terms which do not relate to the Product.

In addition IMMEDICA may also appoint distributors, wholesalers or appoint any Third Party to provide services including sales, logistics and/or regulatory services, all of which shall not be considered Sublicensees.

2.3. **Retained Rights.** IMMEDICA acknowledges and agrees that LICENSOR retains (i) the right to make, have made, and export the Product under the terms of this Agreement, (ii) subject to Section 4.2.2, the right to make, have made and use the Product for internal research purposes within the Field in the Territory, provided such reservation of rights expressly excludes (a) the right to conduct Clinical Studies using the Product in the Territory other than those expressly permitted under this Agreement or as otherwise agreed by the Parties in writing, (b) the right to apply for or to seek Regulatory Approval for the Product in the Territory, and (c) the right to Commercialize the Product in the Territory, and (iii) the right to make, have made, use and export the Product for any and all purposes outside of the Territory.

2.4. **Additional Products.** If during the term of this Agreement (i) LICENSOR or its Affiliate Develops or Commercializes either alone or with a Third Party and or (ii) LICENSOR or its Affiliate acquires the right to Develop and Commercialize in the Territory, any other product comprising an antibody, or another biological therapeutic molecule, conjugated or linked with or otherwise administered with a radioisotope directed to the Target in the Field and such product obtains Regulatory Approval in any country in an indication for which the Product has also obtained Regulatory Approval in a country in the Territory or for which an application for Regulatory Approval has been submitted in a country in the Territory **("Additional Product")** it shall promptly notify IMMEDICA in writing. IMMEDICA shall have the right within [*] of receiving any such notice to request that LICENSOR shall provide such information as IMMEDICA shall reasonably request to enable IMMEDICA to assess the Additional Product. IMMEDICA shall have a period of [*], commencing on its receipt from LICENSOR of the information requested by IMMEDICA, to notify LICENSOR if IMMEDICA wishes to include the Additional Product under the terms of this Agreement. If IMMEDICA notifies LICENSOR that it does wish to include the Additional Product under the terms of this Agreement, then from the date of IMMEDICA's notice, the terms of this Agreement shall apply to such Additional Product including the provisions of Section 6.1 (other than Section 6.1.1) and the Parties shall agree in good faith any necessary amendments to the terms of this Agreement. If during the term of this Agreement (i) LICENSOR or its Affiliate Develops or Commercializes either alone or with a Third Party and or (ii) LICENSOR or its Affiliate acquires the right to Develop and Commercialize in the Territory, any other product comprising an antibody, or another biological therapeutic molecule, conjugated or linked with or otherwise administered with a radioisotope directed to the Target in the Field in an indication for which the Product has not obtained Regulatory Approval in a country in the Territory or for which an application for Regulatory Approval has not been submitted in a country in the Territory **("Other Product")** LICENSOR shall promptly notify IMMEDICA in writing. If LICENSOR or its Affiliate is proposing to outlicense, sell or otherwise transfer the right to Develop and or Commercialize such Other Product in the Territory to a Third Party LICENSOR shall notify IMMEDICA in writing and shall grant IMMEDICA for a period of [*], commencing on the date of IMMEDICA's receipt of such notice, the first right to negotiate in good faith the terms of an agreement pursuant to which IMMEDICA would be granted the right to Develop and Commercialize such Other Product in the Territory. During such [*] period LICENSOR and its Affiliates will not discuss with or grant any Third Party any right to Develop and or Commercialize the Other Product in the Territory.

2.5. **Territory Exclusivity.** LICENSOR shall not and shall ensure that its Affiliates shall not during the term of this Agreement directly or indirectly (i) grant to a Third Party any rights to Commercialize the Product in the Territory for use in the Field or (ii) supply Product to a Third Party (other than Sublicensees if requested by IMMEDICA) for any such purpose.

2.6. **No Additional Rights.** Nothing in this Agreement shall be construed to confer any rights upon IMMEDICA by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of LICENSOR or its Affiliates other than the Licensed Technology.

3. **GOVERNANCE**

3.1. **Alliance Managers.** Within [*] after the Effective Date, each Party shall appoint and notify the other Party of the identity of a representative having the appropriate qualifications, including a general understanding of pharmaceutical development and commercialization issues, to act as its alliance manager under this Agreement (the **"Alliance Manager").** The Alliance Managers shall serve as the primary contact points between the Parties for the purpose of providing each Party with information on the progress and results of the Development and Commercialization of the Product in the Field in the Territory. The Alliance Managers shall also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties with respect to the Product and its Manufacture. Each Party may replace its Alliance Manager with a new representative having the appropriate qualifications at any time upon written notice to the other Party.

3.2. **Joint Steering Committee.**

3.2.1. **JSC Formation and Role.** Within [*] after the Effective Date, the Parties shall establish a joint steering committee (the **"Joint Steering Committee" or "JSC")** for the overall coordination and oversight of the Parties' activities under this Agreement. The role of the JSC shall be to:

(a) review and discuss the overall strategy for the Development and Commercialization of the Product in the Territory;

(b) monitor and discuss the performance and results of the Phase III Clinical Trial and all other Clinical Studies performed by or on behalf of the LICENSOR pursuant to Section 4.2.1;

(c) discuss any Clinical Study using the Product in the Territory proposed by either Party including proposed investigator sponsored studies and any post Regulatory Approval studies aimed at generating real life data with regard to the Product;

(d) review and discuss the Marketing Plan, including the use of any and all Product Trademarks in connection with the Products in the Territory, and any proposed amendments or revisions thereto;

(e) monitor performance of this Agreement as well as progress of the Commercialization activities compared to the goals defined in the Marketing Plan;

(f) act as the point of escalation for issues that cannot be resolved otherwise;

(g) discuss label expansion for additional patient population or indications;

(h) coordinate the audit of any LICENSOR suppliers and subcontractors relevant to the Product in the Territory, as further detailed in Section 7.2.2;

(i) discuss, as applicable, the monitoring of performance under the Manufacturing Agreements, and discuss any proposal by LICENSOR to enter into new agreements with Third Parties relating to the Manufacture of the Product during the term of this Agreement;

(j) discuss any proposal by LICENSOR to enter into a new agreement with a Third Party relating to the Manufacture of the Products or any proposal to amend the Manufacturing Agreements as further described in Section 12.7;

(k) establish sub-committees that may have separate member composition from the JSC with mutually acceptable charters and defined responsibilities to manage key workstreams related to the Parties' activities under this Agreement, including but not limited to Development and Commercial sub-committees;

(1) act as a forum for the Parties to exchange information about the LICENSOR's Development and Commercialization activities in respect of the Product outside the Territory and about IMMEDICA's Commercialization activities in respect of the Product in the Territory;

(m) establish a mechanism for dealing with the on-line presence for the Product inside and outside the Territory in compliance with Applicable Law; and

(n) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.

3.2.2. **Members.** The JSC shall be comprised of an equal number of representatives from each Party. Each Party' s representatives shall be officers or employees of such Party or its Affiliate having sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. Each Party shall initially appoint three (3) representatives to the JSC. Each Party may replace its representatives at any time upon written notice to the other Party. Each Party shall appoint one (1) of its representatives on the JSC to act as the co-chairperson of JSC. The role of the co-chairpersons shall be to preside at the JSC meetings, but the co-chairpersons shall have no additional powers or rights beyond those held by other JSC representatives. Unless otherwise agreed by the Parties, the Alliance Managers from both Parties shall be non- voting members of the JSC.

3.2.3. **Meetings.** The JSC shall hold meetings on a [*] basis during the term of this Agreement for so long as the JSC exists, unless the Parties mutually agree to a different frequency for such meetings. Either Party may also call a special meeting of the JSC in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting and, reasonably in advance of such special meeting, such Party shall provide the JSC with materials adequate to enable an informed discussion. Reasonably in advance of each JSC meeting, the Alliance Managers (or their designees), on an alternating basis, shall prepare and circulate an agenda for such meeting; provided that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JSC may meet in person, by videoconference or by teleconference. No action taken at a JSC meeting shall be effective unless at least one (1) representative of each Party is present or participating in such meeting. The Alliance Managers (or their designees), on an alternating basis, shall be responsible for preparing reasonably detailed written minutes of each JSC meeting and shall send draft meeting minutes to each representative of the JSC for review. The Parties shall agree on meeting minutes promptly, but in any event no later than [*] following receipt thereof; provided that, if the Parties cannot agree as to the content of the meeting minutes by such timeframe, such minutes shall be finalized to reflect any areas of disagreement. Each Party may invite, in addition to its JSC representatives, any number of employees (including employees of Affiliates) and, with the prior written consent of the other Party, not to be unreasonably withheld, any number of Third Parties, to attend JSC meetings as non-voting participants, provided that, prior to attending such meetings, such Third Party participants shall be bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement.

3.2.4. **Decision Making and Escalation.** The JSC shall strive to seek consensus in its actions and decision-making process, and all decisions by the JSC shall be made by unanimous agreement, with each Party's representatives having collectively one (1) vote in all decisions. If the Parties' representatives on the JSC, after reasonable discussion and good faith consideration of each Party's opinions, cannot reach agreement on a matter within the JSC's responsibilities within [*] after the JSC has met and attempted to agree on such matter (or such other period as the Parties may agree upon in writing), then such disagreement shall be referred to the Parties' respective Executive Officers for resolution. Any final decision that the Executive Officers mutually agree to in writing shall be conclusive and binding on the Parties. If the Executive Officers cannot reach agreement on a matter within [*] after such matter has been referred to them by the JSC (or such other period as the Executive Officers may agree upon in writing), then IMMEDICA shall have the tie-breaking vote, and the decision of IMMEDICA's Executive Officer shall be final and binding on the Parties, with respect to any matter concerning Regulatory Approval in the Territory, or safety of the Product in the Territory or Commercialization in the Territory, including regarding the adaptation and localisation of the global marketing and brand strategy for the Product in the Territory, or, subject to Section 4.3.7, pricing strategy, launch sequencing, reference pricing and importation and distribution matters in each case with respect to the Product in the Territory, except that LICENSOR shall have the tie-breaking vote, and the decision of LICENSOR's Executive Officer shall be final and binding on the Parties, with respect to any matter that will have a material adverse impact on (a) the global safety profile of the Product, (b) the procurement or maintenance of any Regulatory Approval in any country or jurisdiction outside of the Territory, (c) changes to the Protocol, and (d) subject to the provisions of Section 4.2, matters concerning the Development Activities of LICENSOR, including the Clinical Studies carried out by LICENSOR in the Territory in accordance with the terms of this Agreement and all decisions regarding whether or not LICENSOR will conduct Additional Clinical Studies and Additional Indication Studies involving the Product.

3.2.5. **Limitations of JSC Authority.** Notwithstanding the foregoing, neither the JSC nor the Party with final decision-making authority as set forth in Section 3.2.4 shall have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with this Agreement; (c) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (d) obligate either Party to violate Applicable Laws or incur any material liabilities or payment obligations.

3.2.6. **Discontinuation of the JSC.** The activities to be performed by the JSC shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC shall continue to exist until the Parties mutually agree to disband the JSC, but in any event the JSC shall be automatically disbanded effective upon the expiration or termination of this Agreement. Once the JSC is disbanded, it shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be responsible for the exchange of information under this Agreement and the decisions of the Alliance Managers shall be decisions as between the Parties (but, with final decision-making authority to continue to be in accordance with Section 3.2.4), subject to the other terms and conditions of this Agreement.

4. TRANSFER OF LICENSED KNOW-HOW, DEVELOPMENT AND COMMERCIALIZATION

4.1. Transfer of Licensed Know-How

4.1.1. Intentionally Omitted.

4.1.2. **Ongoing Transfer.** LICENSOR shall, and shall use diligent efforts to cause any contractors to, promptly transfer to IMMEDICA (or, in the case of contractors, to promptly grant to IMMEDICA a right of reference with respect thereto, if applicable), from time to time during the term of this Agreement, Licensed Know-How that is necessary or useful for the Development or Commercialization of the Product in the Field in the Territory as contemplated in this Agreement, including for the purposes of preparing, filing, and maintaining any Regulatory Approvals in accordance with Section 5.2, to the extent that it has not previously been provided to IMMEDICA hereunder.

4.1.3. **Cooperation.** The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the Licensed Know-How in accordance with this Section 4.1. Without limiting the foregoing, the LICENSOR shall provide all such items in electronic form to the extent the same exists in electronic form and shall provide copies and an opportunity to inspect (and copy) original versions for all other materials comprising such Licensed Know-How (including for example, original patient report forms and other original source data). It is understood that all Licensed Know-How shall be made available to IMMEDICA in English. Upon request by IMMEDICA, the LICENSOR shall, and shall use diligent efforts to cause any contractors (including any contract manufacturers) to, reasonably cooperate with and assist IMMEDICA, at LICENSOR's cost, as may be necessary or desirable in order to allow IMMEDICA to understand the Licensed Know-How and to utilize the Licensed Know-How for the purposes contemplated in this Agreement. Notwithstanding the foregoing, if during the term of this Agreement the Parties agree to transfer responsibility for Manufacturing the Product to IMMEDICA at IMMEDICA's request, any reasonable costs of LICENSOR associated with the transfer of the Manufacturing process for the Product to IMMEDICA shall be reimbursed by IMMEDICA, without prejudice to the provisions of Section 7.8.

4.2. **Development.**

4.2.1. Unless otherwise agreed by the Parties, and except as otherwise provided in this Section 4.2.1 and Section 4.2.3, the LICENSOR shall be solely responsible for the performance of, and all costs relating to, the Development of the Product in the Territory, including the Phase III Clinical Trial. LICENSOR will use Commercially Reasonable Efforts to continue the on-going Phase III Clinical Trial in the manner outlined within the Protocol. If any further Clinical Studies are required by a Regulatory Authority in order to obtain or maintain a Regulatory Approval for the Product (including complying with any paediatric investigation plan or carrying out any post approval safety or efficacy studies) for active, relapsed or refractory AML in patients aged 55 and older (or any variation to the foregoing agreed with a Regulatory Authority) in the Territory (**"Additional Clinical Studies"**), the Parties shall discuss such required Clinical Studies at the JSC. If the reasonably estimated costs of carrying out such Clinical Studies is less than [*] the LICENSOR shall carry out such Clinical Studies at its cost as soon as reasonably practicable. If the reasonably estimated costs of carrying out Additional Clinical Studies is more than [*] the Parties shall discuss in good faith and agree how such Clinical Study should be carried out and how the costs of such Clinical Study in excess of [*] should be shared between the Parties, provided that LICENSOR shall not be obligated to perform any such Clinical Study in the absence of agreement between the Parties. Unless otherwise agreed by the Parties, any such Clinical Study shall be designed to include no more than the minimum number of subjects required by the applicable Regulatory Authority. Subject to the foregoing, the LICENSOR shall not, and shall not assist, enable or authorize any Affiliate or Third Party to, undertake any Clinical Study of the Product within the Territory in active, relapsed or refractory AML in patients aged 55 and older (or any variation to the foregoing agreed with a Regulatory Authority) or any other indication that has obtained Regulatory Approval in the Territory without the prior written consent of IMMEDICA, which consent shall not be unreasonably withheld, conditioned or delayed. Any protocol for such proposed Clinical Study within the Territory shall be subject to the prior written approval of IMMEDICA, which approval shall not be unreasonably withheld, conditioned or delayed.

LICENSOR shall provide the JSC with quarterly reports on the status and progress of all such Development activities. Upon completion of each Clinical Study (including all Additional Indication Studies) relating to the Product, LICENSOR shall provide the JSC with a final clinical study report, including all raw data LICENSOR receives or has a right to receive in respect of such Clinical Study. LICENSOR shall use diligent and reasonable efforts to provide to IMMEDICA all other Product-related data and information requested by any Regulatory Authority. In addition, the LICENSOR shall, promptly upon filing, provide a complete and accurate copy of all material Regulatory Filings for the Product submitted to the US Food and Drug Administration for review by IMMEDICA. Subject to the provision of the data and information by the LICENSOR set out in this Section 4.2.1, and notwithstanding anything to the contrary in this Section 4.2.1, IMMEDICA shall bear all responsibility and expense for filing all Regulatory Filings in the Territory in IMMEDICA's name and obtaining Regulatory Approval for the Product in the Territory. IMMEDICA will undertake such activities at its sole expense and shall provide to LICENSOR reports regarding IMMEDICA's progress within [*] following the expiration of each Calendar Year. In addition, IMMEDICA shall, promptly upon filing, provide a complete and accurate copy of all material Regulatory Filings (excluding any Regulatory Filings relating to pricing and reimbursement in the Territory) for the Product submitted to Regulatory Authorities in the Territory for review by LICENSOR. IMMEDICA shall provide to LICENSOR copies of all pricing and reimbursement approvals obtained by IMMEDICA for the Product in the Territory. If the JSC approves any investigator sponsored Clinical Studies to be conducted in the Territory IMMEDICA shall be responsible for entering into any agreements with the applicable investigators for such approved studies. Such agreements will be substantially based on a template agreement that will be reviewed and approved by the JSC. Upon completion of each such Clinical Study relating to the Product, IMMEDICA shall provide the JSC with a final clinical study report, including all raw data (in relation to raw data for interventional studies but not raw data for non- interventional studies) IMMEDICA receives or has a right to receive in respect of such Clinical Study. IMMEDICA shall use diligent and reasonable efforts to provide to LICENSOR all other Product-related data and information in the possession or control of IMMEDICA requested by any regulatory authority outside the Territory in relation to the Product.

4.2.2. **Development in new indications by LICENSOR inside the Territory.** If the LICENSOR or any Affiliate or Third Party authorized by the LICENSOR intends to conduct a Clinical Study for the Product in the Territory for an indication in addition to active, relapsed or refractory AML in patients aged 55 and older (including complying with any paediatric investigation plan) or any other indication that has, at the relevant date, not been granted Regulatory Approval in the Territory **("Additional Indication Study"),** the LICENSOR shall provide prior written notice thereof, together with a copy of the proposed protocol for such Additional Indication Study, to IMMEDICA. The LICENSOR shall provide IMMEDICA a reasonable opportunity to comment on any such proposed protocol and consider in good faith (but without any obligation to incorporate or adopt) any comments provided by IMMEDICA within [*] after delivery of the proposed protocol to IMMEDICA. Subject to the foregoing provisions LICENSOR shall be entitled to carry out Additional Indication Studies in the Territory.

4.2.3. **Development by IMMEDICA.** IMMEDICA shall be responsible for carrying out, at IMMEDICA's sole cost, all observational studies, registers and health economic studies in relation to the Product in Territory (except any post marketing studies required to obtain or maintain a Regulatory Approval for the Product which studies shall be the responsibility of the LICENSOR) and shall keep LICENSOR regularly informed through the JSC with regard to any such studies that it conducts. Upon completion of each such study, IMMEDICA shall provide the JSC with a final study report, including all raw data (in relation to raw data for interventional studies but not raw data for non-interventional studies) IMMEDICA receives or obtains, has a right to receive or obtain, in respect of such study.

4.2.4. **Co-Operation.** Each Party will keep the other Party reasonably informed through the JSC as to its regulatory strategy for obtaining regulatory approval of the Product, in the case of the LICENSOR outside the Territory and in the case of IMMEDICA inside the Territory. The LICENSOR may inform its licensees outside the Territory of IMMEDICA's Development activities in respect of the Product in the Territory solely for the purpose of the Development and Commercialization of the Product in such licensees' respective territory outside the Territory. Each Party shall cooperate as reasonably requested by the other Party in an effort to ensure that the Parties' Development activities, as they relate to obtaining regulatory approval of the Product are coordinated worldwide, provided however that this shall not be interpreted or construed as limiting IMMEDICA's and the LICENSOR's rights and obligations under this Agreement.

4.2.5. The Parties shall each ensure that they comply with all Applicable Laws with respect to the performance of their obligations hereunder and in the performance of all Clinical Studies relating to the Product.

4.2.6. **Prohibition on Development of Competing Products.** IMMEDICA shall not, during the term of this Agreement, Develop or Commercialize any pharmaceutical product for conditioning treatment, inside or outside the Territory, itself or through or with a Third-Party, that competes with an indication approved under a Regulatory Approval for the Product, except upon the prior written consent of the LICENSOR.

4.3. **Commercialization.** IMMEDICA shall be solely responsible for the Commercialization of the Product in the Territory. IMMEDICA will undertake such activities at its sole expense.

4.3.1. **Marketing Plan.** No later than [*] before the expected launch of the Product in the Territory IMMEDICA will prepare an initial marketing plan for the Product **("Marketing Plan")** according to IMMEDICA's marketing planning process, but will include at a minimum, medical education and communication, brand strategy, brand positioning, key messages, public relations, access, and reimbursement, sales and distribution strategies. The LICENSOR will notify IMMEDICA of LICENSOR's global marketing strategy for the Product on an annual basis. Such strategy shall include medical education and communication, brand strategy, brand positioning, key messages, public relations, access, and reimbursement, sales and distribution strategies.

4.3.2. **Review and Comment on Marketing Plan.** IMMEDICA will submit the final draft of the initial and any materially updated Marketing Plan to LICENSOR, via the JSC, for review and comment. LICENSOR will provide comments on such draft to the JSC within [*] after receipt. The JSC shall meet to review the Marketing Plan and any comments provided by LICENSOR, and IMMEDICA will reasonably consider such comments, prior to finalization and implementation of the Marketing Plan. Notwithstanding anything herein to the contrary, if LICENSOR notifies IMMEDICA that the Marketing Plan conflicts with LICENSOR's global commercialization strategy, IMMEDICA shall not finalize and implement the Marketing Plan until such conflict is resolved to the satisfaction of both Parties.

4.3.3. **Diligence Obligations.** IMMEDICA shall itself, or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Commercialize the Product in the Territory, including using Commercially Reasonable Efforts to perform the activities set forth under each Marketing Plan. All efforts of IMMEDICA's Affiliates and Sublicensees will be considered efforts of IMMEDICA for the purpose of determining IMMEDICA's compliance with its obligations under this Section 4.3.3.

4.3.4. **Shipment and Policing of Product Outside the Territory.** IMMEDICA may not deliver or tender (or cause to be delivered or tendered) any Product outside of the Territory. If IMMEDICA becomes aware that any customer of the Product in the Territory (including a distributor, wholesaler or health group) is reselling or distributing any quantities of the Product acquired from IMMEDICA outside the Territory, then IMMEDICA shall notify LICENSOR in writing and take reasonable steps to cause such customer to cease reselling or distributing the Product outside the Territory. If IMMEDICA receives any order from a prospective purchaser located outside the Territory, IMMEDICA shall not accept any such orders and shall promptly inform LICENSOR of such order(s).

4.3.5. **Shipment and Policing of Product Inside the Territory.** Except with respect to the delivery of Product for use in connection with Clinical Studies in the Territory and sales of the Product by LICENSOR to IMMEDICA under this Agreement, the LICENSOR may not deliver or tender (or cause to be delivered or tendered) any Product inside the Territory. If the LICENSOR becomes aware that any customer of the Product outside of the Territory (including a distributor, wholesaler or health group) is reselling or distributing any quantities of the Product inside the Territory, then the LICENSOR shall notify IMMEDICA in writing and take reasonable steps to cause such customer to cease reselling or distributing the Product in the Territory. If the LICENSOR receives any order from a prospective purchaser located inside the Territory, the LICENSOR shall not accept any such orders and shall provide prompt written notice of such order(s) to IMMEDICA.

4.3.6. **Labeling and Artwork.** Cutter guides (technical drawings of the Artwork mock-ups) will be provided by LICENSOR to IMMEDICA. IMMEDICA shall be responsible for updating the cutter guides and the creation of printer ready labeling mock-ups in the Territory according to local regulations and guidelines. In the event that IMMEDICA proposes changes to the labeling or packaging of the Product, it shall provide LICENSOR with justification for the proposed change, revised mock-ups for printing and clear timelines for the implementation of such updates The actual cost of implementing such change will be at IMMEDICA's sole cost and expense, including any materials made obsolete by IMMEDICA's changes to the artwork, unless such change was requested by the LICENSOR, in which case such cost and expense shall be at the LICENSOR's sole cost and expense. All labeling, artwork, packaging and proposed changes thereto shall at all times comply with Applicable Laws.

4.3.7. **Pricing and Reimbursement.** IMMEDICA shall be solely responsible for all pricing and reimbursement matters relating to the Product in the Territory including all related discussions with Regulatory Authorities including relevant pricing and reimbursement bodies; provided that if IMMEDICA supplies the Product in the Territory at a price that would cause the LICENSOR to incur a loss on its fully burdened cost of Manufacture of the Product as notified to IMMEDICA prior to the date of any such supply, IMMEDICA shall reimburse LICENSOR for any such shortfall. Notwithstanding the foregoing sentence, if approved by the JSC, IMMEDICA shall be entitled to provide Product at no charge for the purpose of any investigator sponsored Clinical Studies conducted in the Territory with the JSC's prior approval, or as donations or the like or as "treatment IND sales", "named patient sales", "compassionate use sales", or pursuant to any expanded access programs, or any equivalent; provided that the quantities of Product provided at no charge do not exceed the quantities approved by the JSC for such purpose. IMMEDICA will reimburse LICENSOR for any Product supplied that exceeds quantities approved by the JSC for such purpose. Each Party shall promptly provide to the other Party a copy of any cost effectiveness model and/or value dossier developed by such Party relating to a Product for the other Party's review.

4.3.8. **Co-Operation.** Each Party will keep the other Party reasonably informed through the JSC as to its Development and Commercialization activities in respect of the Product, in the case of the LICENSOR outside the Territory and in the case of IMMEDICA inside the Territory. The LICENSOR may inform its licensees outside the Territory of IMMEDICA's Commercialization activities in respect of the Product in the Territory solely for the purpose of the Development and Commercialization of the Product in such licensees' respective territory outside the Territory. The will keep IMMEDICA informed of its own and such licensee's Development and Commercialization activities in respect of the Product solely for the purpose of IMMEDICA's Commercialization of the Product in the Territory. Each Party shall cooperate as reasonably requested by the other Party in an effort to ensure that the Development and Commercialization of the Product is coordinated worldwide, provided however that this shall not be interpreted or construed as limiting IMMEDICA's and the LICENSOR's rights and obligations under this Agreement. The Parties will cooperate in good faith with regard to agreeing on matters that relate to the Product inside and outside the Territory such as attendance at international conferences. LICENSOR shall ensure that LICENSOR's, its Sublicensees' and/or Affiliates' engagement with healthcare professionals in relation to the Product is in accordance with the Applicable Law in the country in the Territory where such healthcare professional is normally located and IMMEDICA shall ensure that IMMEDICA's, its Sublicensees' and/or Affiliates' engagement with healthcare professionals in relation to the Product is in accordance with the Applicable Law in the country outside the Territory where such healthcare professional is normally located. Each Party shall keep the other reasonably informed with regard to such matters provided that this obligation shall not require the Parties to keep each other informed in relation to incidental or immaterial interactions with healthcare professionals at international conferences.

5. **REGULATORY MATTERS**

5.1. **Marketing Authorization Holder.** Subject to IMMEDICA's obligations upon termination pursuant to Section 15.6, IMMEDICA shall be the holder and owner of all Regulatory Approvals in the Territory. Promptly and in any event within [*] of the Effective Date, LICENSOR shall assign the Orphan Drug Designation for the Product in the Territory to IMMEDICA.

5.2. **Maintenance of Marketing Authorizations.** With respect to the Product, IMMEDICA shall have the right, at its sole discretion and cost and expense, to prepare, file and maintain such Regulatory Approvals in the Territory throughout the term of this Agreement including obtaining any variations or renewals thereof. Without limiting the foregoing, IMMEDICA shall be responsible for filing and shall use its Commercially Reasonable Efforts to file the marketing authorization application for the Product with the EMA. LICENSOR shall provide IMMEDICA with all information in the possession or control of LICENSOR or its Affiliates or licensees or assignees of the Product outside the Territory reasonably required by IMMEDICA to prepare, file and maintain any such application and any Regulatory Approval including any filings for Regulatory Approval for the Product made by or on behalf of LICENSOR, its Affiliates or its licensees or assignees outside the Territory. LICENSOR shall also, at no cost to IMMEDICA (as long as such costs are reasonable), make reasonably available its personnel and subject matter experts with the knowledge of the Development of the Product to consult with IMMEDICA and to provide reasonable assistance in a timely manner to IMMEDICA in connection with any of the foregoing, including but not limited to supporting IMMEDICA's preparation of the EU marketing authorization application for the Product (through the provision of documentation for and attendance at pre-submission meetings with EMA as relevant) and supporting Il'v1MEDICA with respect to the EMA assessment of the application and any questions raised by the EMA including attending meetings with the EMA to answer any such questions.

5.3. **Interaction with Regulatory Authorities.** After the Effective Date, each Party shall provide to the other Party a copy of any material correspondence or materials that it receives from or submits to a Regulatory Authority or any material decision made by a Regulatory Authority regarding, in each case, the Product, in respect of IMMEDICA, in the Territory and, in respect of LICENSOR, outside of the Territory. LICENSOR shall use reasonable efforts to cause that its licensees or assignees in relation to the Product outside the Territory to provide such information as is required by Section 5.2 above and this Section 5.3 to LICENSOR to enable LICENSOR to comply with its obligations. If such correspondence received by a Party is not in English, then such copy will include a summary in English of all material matters addressed thereby. IMMEDICA shall provide reasonable advance written notice to LICENSOR of all material meetings, conferences, or calls with Regulatory Authorities concerning the Product (excluding meetings, conferences, or calls with Regulatory Authorities relating to pricing and reimbursement of the Product), and LICENSOR shall be permitted to have appropriate representatives attend all such meetings, conferences, or calls to the extent permitted by Applicable Law. IMMEDICA shall provide LICENSOR with copies of any materials relating to any material regulatory matter relating to the Product (excluding materials relating to pricing and reimbursement) and, when reasonably practicable, shall provide copies of any documents to be presented to any Regulatory Authority in respect of such matters prior to their presentation thereto. In addition, during the term of the Agreement and with respect to all Product supplied and purchased under this Agreement, after the termination of this Agreement, each Party shall promptly (and in any case within [*]) notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from a concerned Regulatory Authority which may affect the safety or efficacy claims of the Product or the continued marketing of the Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action. The materials to be provided under this Section 5.3 with respect to material interactions with any Regulatory Authority will be forwarded to the other Party promptly after receipt.

5.4. **Right of Reference.** Subject to the terms and conditions set forth in this Agreement, (i) LICENSOR hereby grants to IMMEDICA a fully paid, exclusive right and license to reference any Regulatory Approvals Controlled by LICENSOR or its Affiliates for the Product outside the Territory for the purpose of obtaining Regulatory Approval of the Product in one or more countries in the Territory, and (ii) IMMEDICA hereby grants to LICENSOR, its Affiliates and its licensees a fully paid, exclusive right and license to reference any Regulatory Approvals Controlled by IMMEDICA or its Affiliates or Sublicensees for Product inside the Territory for the purpose of obtaining Regulatory Approval of the Product in one or more countries outside the Territory; provided that if the exercise of the right of reference under this Section 5.4(i) triggers any inspection or audit of LICENSOR (or its Affiliates or licensees outside the Territory) then IMMEDICA will reimburse LICENSOR (or its Affiliates or licensees outside the Territory) for the costs incurred by LICENSOR (or its Affiliates or licensees outside the Territory) in respect of such inspection or audit; and provided further that if the exercise of the right of reference under this Section 5.4(ii) triggers any inspection or audit of IMMEDICA then LICENSOR will reimburse IMMEDICA for the costs incurred by IMMEDICA in respect of such inspection or audit.

5.5. **Pharmacovigilance.** The LICENSOR will be responsible for managing the global safety database for the Product. Within [*] after the Effective Date, the Parties shall enter into a pharmacovigilance agreement pursuant to which the Parties will mutually exchange adverse events or other safety data within and outside of the Territory as required for each Party to fulfill the relevant requirements in accordance with Applicable Law. IMMEDICA may maintain its own safety database for the Product for safety data collection, evaluation and reporting as well as for purposes of safety surveillance, risk management as required in the Territory. The LICENSOR shall provide information on individual case safety reports from the global safety database for the Product to IMMEDICA to be further specified in the pharmacovigilance agreement. The Parties shall mutually maintain a procedure for reconciliation of safety data between the safety databases of the Parties. As between the Parties: (a) IMMEDICA shall be responsible for the pharmacovigilance surveillance, risk management and timely reporting of adverse drug reactions/experiences, and safety data relating to the Product to the appropriate Regulatory Authorities in the Territory in accordance Applicable Law in the Territory; and (b) LICENSOR or its licensee(s) shall be responsible for the pharmacovigilance surveillance, risk management and timely reporting of adverse drug reactions/experiences, and safety data relating to the Product to the appropriate Regulatory Authorities outside the Territory, in each case in accordance with Applicable Laws. The Parties shall cooperate with each other with respect to their respective pharmacovigilance responsibilities and any safety related changes to the Product label or other additional pharmacovigilance or risk minimization activities.

5.6. **Promotional Materials.** IMMEDICA shall be responsible for developing the promotional materials for use in Commercializing the Product in the Territory in accordance with Applicable Law and shall ensure that such materials are consistent with LICENSOR's global marketing strategy for the Product as notified to IMMEDICA in accordance with Section 4.3.1. If IMMEDICA proposes to use promotional materials that deviate significantly from any such global marketing strategy such materials will be submitted to LICENSOR for review and approval prior to use. IMMEDICA shall own all rights in any promotional materials it creates. IMMEDICA shall deliver copies of all promotional materials it creates for the Product to the LICENSOR prior to distribution or use.

5.7. **Medical Inquiries.** Following grant of the first Regulatory Approval for the Product in the Territory IMMEDICA will be responsible for handling all medical questions or inquiries in respect of the Product in the Territory. The LICENSOR shall promptly forward any and all medical questions or inquiries which it receives in respect of the Product in the Territory to IMMEDICA in accordance with Applicable Laws. The LICENSOR shall be responsible for handling all medical questions or inquries in respect of the Product outside of the Territory. IMMEDICA shall promptly forward any and all medical questions or inquiries which it receives in respect of the Product outside the Territory to the LICENSOR in accordance with Applicable Laws. The Parties shall cooperate and establish the procedures reasonably necessary (such as periodic meetings via teleconference or videoconference) to ensure the consistency and correctness of the medical information provided by the Parties.

6. **PAYMENT TERMS**

6.1. **Payment Terms .**

6.1.1. **Upfront Payment.** IMMEDICA shall pay to LICENSOR an upfront payment as set forth in Schedule B within [*] of the Effective Date, subject to the receipt of the applicable invoice from the LICENSOR.

6.1.2. **Milestone Payments.** IMMEDICA shall notify LICENSOR [*] upon achievement of each Milestone. IMMEDICA shall pay to LICENSOR each applicable milestone payment set forth in Schedule B (each, a **"Milestone Payment")** within [*] after the achievement of such Milestone is notified to LICENSOR, subject to the receipt of the applicable invoice from the LICENSOR.

6.1.3. **Royalty Payments.** On a country-by-country basis, from the date of First Commercial Sale in such country in the Territory, and for the remainder of the term of this Agreement, IMMEDICA shall pay to LICENSOR the royalties set forth in Schedule B (collectively, **"Royalties")** within [*] following the expiration of each Calendar Quarter. All payments shall be accompanied by a report that includes for the applicable Calendar Quarter the following information on a country-by-country basis: (a) gross sales of Product in United States Dollars (including any foreign exchange rates employed); (b) Net Sales of Product (including any foreign exchange rates employed); (c) Deductions taken from gross sales (by category as set forth in the definition of Net Sales) to arrive at the Net Sales calculation (including any foreign exchange rates employed); and (d) the Royalties payable to LICENSOR in United States Dollars and in Euros (€) (including any foreign exchange rates employed).

6.1.4. **Other Payments.** IMMEDICA shall pay to LICENSOR any other amounts due under this Agreement within [*] following receipt of invoice, subject to the receipt of the applicable invoice from the LICENSOR.

6.1.5. **Late Payments.** Any late payments shall bear interest, to the extent permitted by law, at [*] above the Euribor three months rate of interest on the date payment is due.

6.1.6. **Payments under Existing Agreements.** LICENSOR shall be responsible for making all payments of any sums due under the Existing Agreements to the applicable counterparty to the agreement in respect of the activities conducted under this Agreement including any milestone or royalty payments.

6.2. **Payment Method.**

6.2.1. For the purpose of calculating any sales milestone payment threshold expressed in Euros, any Net Sales that are received by IMMEDICA in currencies other than Euros shall be converted into Euros at the average (mean) monthly closing prevailing foreign exchange rate published by the European Central Bank (or any other qualified source that is acceptable to both Parties) during the applicable Calendar Quarter in which such amounts were booked, or for periods less than a Calendar Quarter, the average (mean) prevailing foreign exchange rate published by the European Central Bank during such period.

6.2.2. All payments from IMMEDICA to LICENSOR shall be made in US Dollars. For the purpose of calculating Royalties and Milestone Payments not expressed in US Dollars, Net Sales and Milestone Payments shall be converted into US Dollars at the average (mean) daily closing prevailing foreign exchange rate published by the European Central Bank (or any other qualified source that is acceptable to both Parties) (a) in the case of Royalties, during the applicable Calendar Quarter in which such Royalty is payable; and (b) in the case of Milestone Payments, on the date the Milestone triggering such Milestone Payment is achieved. Each such payment shall be made by wire transfer to the credit of such bank account as may be designated by LICENSOR in writing to IMMEDICA. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

6.3. **Taxes.**

6.3.1. It is understood and agreed between the Parties that any amounts payable by IMMEDICA to LICENSOR hereunder are exclusive of any and all applicable sales, use, VAT, GST, excise, property, and other taxes, levies, duties or fees (collectively, **"Taxes").** IMMEDICA shall be responsible for billing and collection from its customers and remitting to the appropriate taxing authority any and all Taxes which it is required to collect or remit. Each Party will be responsible for their own income and property taxes.

6.3.2. If IMMEDICA is required to make a payment to LICENSOR subject to a deduction of tax or withholding tax (a **"Withholding Tax Requirement"),** then to the extent such amounts are deducted, withheld and paid by or on behalf of IMMEDICA to the appropriate taxing authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the LICENSOR. IMMEDICA shall provide LICENSOR with official receipts issued by the appropriate governmental agency to IMMEDICA.

6.3.3. The Parties agree to cooperate and produce on a timely basis any tax forms or reports and any other documentation required to prove treaty eligibility (which may vary depending on the applicable country), reasonably requested by the other Party in connection with any payment made by IMMEDICA to LICENSOR under this Agreement.

7. MANUFACTURE AND SUPPLY

7.1. **Purchase and Sale of Product.** During the term of this Agreement and in accordance with the terms and conditions set forth herein, (a) the LICENSOR shall have Product Manufactured and sell and deliver to IMMEDICA Product packaged and labeled and ready for use; and (b) IMMEDICA shall order, purchase, and take delivery of [*] exclusively from the LICENSOR. For the avoidance of doubt, other than the serialization of the Product (which as at the Effective Date the Parties agree is not required), the foregoing does not operate to grant any license to IMMEDICA to Manufacture or have Manufactured the Product.

7.2. **Manufacturing Standards and Practices.**

7.2.1. The LICENSOR shall have Product Manufactured for IMMEDICA at the Facility in accordance with the Specifications, GMP, all Applicable Laws, the Quality Agreement and the terms and conditions of this Agreement. LICENSOR shall consult with IMMEDICA prior to any change to the Facility that would impact the Regulatory Approval for the Product in the Territory (including any change that would require a variation of the Regulatory Approval). LICENSOR shall provide notice and rationale of any such change to IMMEDICA as promptly as practicable to allow IMMEDICA to file and seek approval of any variation or amendment to a Regulatory Approval before such change is implemented. Justification for the proposed changes as well as any updated sections to the Regulatory Dossier Module 3 (CMC) documentation required to support such variation will be provided to IMMEDICA by LICENSOR at LICENSOR's expense. The Specifications will not be amended or modified unless agreed by both Parties in writing. If any Regulatory Authority requires a change to the Specifications or if any such change is required by a change in Applicable Law the Parties will discuss and agree how to implement such change. LICENSOR shall, and shall use reasonable efforts to cause its Third Party suppliers to, support IMMEDICA in gathering any information and data (including through carrying out stability studies) required for IMMEDICA to fullfil its obligation to submit such regulatory variations, or fullfil obligations associated with such variations (including 'Post approval commitments'). IMMEDICA shall pay the filing fee associated with any application by IMMEDICA for a variation to a Regulatory Approval for the Product in the Territory. Any other costs, fees or expenses incurred as a result of having to file an application for a variation as a result of such a change in the Facility or change to the Specifications or a requirement of a Regulatory Authority shall be borne by (i) IMMEDICA if such variation is required as a result of a request from IMMEDICA, a change or requirement of a Regulatory Authority in the Territory or a change in Applicable Laws in the Territory and (ii) in all other cases shall be borne by LICENSOR. For clarity, except as otherwise required to comply with Applicable Laws, until such time as a variation is approved by the applicable Regulatory Authority LICENSOR shall continue to supply the Product to IMMEDICA in accordance with the unamended Specification and Regulatory Approval.

7.2.2. IMMEDICA shall have the right, at its sole expense, to audit the LICENSOR for compliance with Applicable Laws, GMP and the terms of the Quality Agreement on reasonable prior written notice during normal business hours and not more than [*] in each Calendar Year. In addition, and subject to reasonable confidentiality obligations, IMMEDICA shall have the right, at its sole expense, to join with LICENSOR during its annual audit of LICENSOR's suppliers and subcontractors for compliance with Applicable Laws, GMP and the terms of the Quality Agreement and any for-cause audits and audits required by Applicable Law. The LICENSOR shall co-operate in good faith in scheduling, attending at and assisting in all IMMEDICA audits. To assist in such scheduling arrangements, the LICENSOR shall notify IMMEDICA at least [*] in advance (or, in the case of for-cause audits, as soon as reasonably practicable) in the event that the LICENSOR intends to conduct any audit at any suppliers or subcontractors and, if so desired by IMMEDICA, the LICENSOR shall use its reasonable efforts to allow IMMEDICA to attend and fully participate in such audit. In the event that IMMEDICA audits a LICENSOR supplier or subcontractor, the LICENSOR has the right to be on site during the audit and act as an observer between IMMEDICA and such supplier or subcontractor. The LICENSOR may charge its reasonable costs and expenses for such attendance if such audit takes place more than [*] per year, unless IMMEDICA identifies a material defect in the LICENSOR's or any subcontractor's or supplier's performance of its obligations under this Agreement, justifying an audit. If IMMEDICA or its representatives notify the LICENSOR of any defects in the LICENSOR's or any subcontractor's or supplier's performance of its obligations under this Agreement, including non-compliance with any Applicable Laws, the LICENSOR shall correct, or cause its suppliers or subcontractors to correct, the defects as soon as practicable at the LICENSOR's expense and shall provide such evidence as IMMEDICA may reasonably request that such defects have been remedied.

7.2.3. The LICENSOR shall provide IMMEDICA with certificates of analysis for all Product supplied hereunder based upon a reference standard established by the LICENSOR and reasonably acceptable to IMMEDICA.

7.2.4. Upon the reasonable request of IMMEDICA following the release and shipment of any Product supplied under this Agreement, the LICENSOR shall provide IMMEDICA with such information, including analytical and manufacturing documentation, batch records for Product and stability data, in each case requested by IMMEDICA regarding quality control of such Product. Without limiting the foregoing obligations, IMMEDICA acknowledges and agrees that IMMEDICA is responsible for the final disposition and release of Product in the Territory.

7.2.5. All information disclosed or obtained pursuant to this Section 7.2 shall constitute Confidential Information of the LICENSOR.

7.3. **Quality Assurance.** Within [*] of the Effective Date, the Parties shall enter into a quality assurance agreement for the Product (the **"Quality Agreement").** The Quality Agreement shall address the standard quality terms of supply and relevant other terms, including, terms relating to specifications, product warranties, quality testing, storage, shipment, labelling, quality controls and regulatory matters.

7.4. **Materials.** Unless otherwise agreed to in writing by the Parties, the LICENSOR shall be responsible at its expense for obtaining all Materials in reasonable quantities consistent with the LICENSOR's supply obligations under the then-current purchase order, on timelines that enable the LICENSOR to meet its delivery and supply obligations under all applicable purchase orders and this Agreement, taking into account the forecast demand for Product as reflected in the most recent Forecast.

7.5. **Handling and Storage.** The LICENSOR shall and shall cause its suppliers and subcontractors to handle and store the Product and the Materials for the Product pursuant to GMP and otherwise in a commercially reasonable manner and in accordance with, as applicable (a) the Specifications, (b) Applicable Laws, including GMP, and (c) the terms of the Quality Agreement. LICENSOR shall and shall cause its suppliers and subcontractors to comply with such other practices and procedures mutually agreed upon in writing between the LICENSOR by IMMEDICA.

7.6. **Packaging and Labeling.** As between the Parties, LICENSOR shall be solely responsible for packaging and labeling the Product for sale and distribution in the Territory. IMMEDICA shall be responsible for providing to LICENSOR artwork for the packaging to be applied to the Product by LICENSOR.

7.7. **Forecasts and Orders.**

7.7.1. Not less than [*] prior to the first day of each Calendar Quarter (commencing with the first Calendar Quarter in which IMMEDICA orders Product from the LICENSOR hereunder), IMMEDICA shall prepare and provide the LICENSOR with a written forecast of its good faith estimated requirements for Product for each of [*] (each a **"Forecast**"). IMMEDICA shall not increase or decrease the quantity estimated for [*] of each Forecast from the quantity estimated for such periods in the previous Forecast. The quantities estimated for all subsequent Calendar Quarters of each Forecast shall be non-binding, and for planning purposes only. By way of example, if IMMEDICA issues a forecast on [*], [*] shall be binding on the Parties and the forecasts for [*] shall not be binding on the Parties. In addition, IMMEDICA will provide on a country-by-country basis its good faith estimated number of patients to be treated in the Forecast for the purposes of LICENSOR providing dosimetric doses of the Product. LICENSOR will supply dosimetric doses based on such Forecast of the Product in a manner it reasonably believes most efficient, provided however, it will ensure that dosimetric doses are supplied to all identified patients in accordance with the terms of this Agreement. Therapeutic doses of the Product will be supplied on a per patient basis pursuant to the terms of this Agreement.

7.7.2. The LICENSOR shall be required to supply the quantity of Product ordered by IMMEDICA under this Section 7.7 in any Calendar Quarter up to the quantity forecasted for the [*] of the most recent Forecast in a manner that is reasonably practical given the nature of the Product. If IMMEDICA's orders in any Calendar Quarter exceed the quantity forecasted for the [*] of the most recent Forecast, the LICENSOR shall use commercially reasonable efforts to supply such excess. The LICENSOR shall use commercially reasonable efforts to meet IMMEDICA's delivery requirements specified in accordance with Section 7.7.3. In the event of a shortfall, the LICENSOR shall promptly inform IMMEDICA and use Commercially Reasonable Efforts to apportion Product among IMMEDICA, the LICENSOR, and its other customers on a [*] according to their respective forecasts for the relevant period provided always that such forecasts were proposed in good faith. The LICENSOR shall not give priority of supply to its requirements or its licensees requirements for the Product outside the Territory.

7.7.3. IMMEDICA shall make all purchases under this Section 7.7 by submitting firm purchase orders to the LICENSOR. On a [*] basis, IMMEDICA shall submit such purchase order in writing in a form reasonably acceptable to the LICENSOR, and shall specify the quantity of Product ordered, the place of delivery and the required delivery date therefor, which shall not be less than [*] from after the date of such purchase order. On a continual basis, IMMEDICA shall inform LICENSOR as soon as practical of identified potential patient and when a dosimetric dose of Product has been administered. Except as otherwise expressly provided in this Agreement, the LICENSOR shall be paid for its supply of the Product via the royalty paid by IMMEDICA under Section 6.1.3.

7.7.4. During the Term of this Agreement, to the extent that IMMEDICA orders a quantity of Product that is less than the quantity specified in the binding [*] of the Forecasts provided under Section 7.7.1, IMMEDICA shall refund LICENSOR's wasted out-of pocket costs of buying iodine 131 and/or reserving non-cancellable manufacturing slots to manufacture Product that was not subsequently ordered, subject to the provision by LICENSOR of appropoirate evidence of such costs and to the extent that such iodine 131 or such manufacturing slots cannot be reused or cancelled by LICENSOR.

7.8. **Delivery and Acceptance.**

7.8.1. All Product supplied under this Agreement shall be shipped [*] (Incoterms 2020) to the destination port designated by IMMEDICA in its purchase order, which shall be in the European Union. Any change in the location of delivery shall require the consent of both Parties, such consent not to be unreasonably withheld or delayed. Title to the Product purchased by IMMEDICA hereunder shall pass to IMMEDICA upon delivery at the destination port. IMMEDICA shall be responsible for import duties, import clearance and acting as the importer for such Product.

7.8.2. The LICENSOR shall insure the Products during transit. The LICENSOR and IMMEDICA shall cooperate to ensure all import clearances and other taxes, duties and formalities are paid and in place prior to delivery.

7.8.3. During the term of this Agreement, the LICENSOR agrees and undertakes to maintain a minimum stock of the Materials required to Manufacture the Product with the exception of 131-1 radioisotope equal to the amount required to Manufacture or have Manufactured [*] supply of Product for the Territory in accordance with the most recent Forecast.

7.8.4. If the LICENSOR, at any time during the Manufacturing process, becomes aware that for any reason the LICENSOR will not be able to deliver to IMMEDICA the agreed quantity of conforming Product on the agreed delivery date in accordance with the terms of any purchase order or this Agreement (a **"Delay"),** or any Delay is likely to occur (an **"Anticipated Delay"),** then the LICENSOR shall use its reasonable efforts to minimize, cure or overcome such Delay and/or Anticipated Delay as soon as reasonably possible. Promptly upon the LICENSOR first becoming aware of any Delay or Anticipated Delay, it shall notify the JSC and the IMMEDICA Alliance Manager of such fact in writing. The JSC shall convene a meeting as soon as reasonably possible following such notice, to consider what steps should be taken to avoid or mitigate such Delay and/or Anticipated Delay and to develop a plan to avoid any Delay occurring, in the event of an Anticipated Delay, to mitigate the effects of any Delay and how to prevent any Delay and/or Anticipated Delay from occurring in the future, including the appointment of a Third Party Manufacturer or the allocation of more capacity to the Manufacture of Products for IMMEDICA. In the event that a Third Party Manufacturer is appointed, the costs of the associated technology transfer shall be borne solely by the LIC: NSOR and shall be subject to the agreement of a high-level plan for the full and complete transfer of the relevant manufacturing Know- How and technology to such Third Party Manufacturer. In the event of an issue at the Facility, or a supply shortage of the Product affecting IMMEDICA and/or the LICENSOR, its Affiliates and other licensees and Sublicensees, then the LICENSOR shall ensure that IMMEDICA receives a fair and reasonable *pro rata* share of any Product based on the quantities of Product included in purchase orders placed in the last Calendar Year before such Facility issue or supply shortage occurred.

7.8.5. In the event of a Supply Failure or a Bankruptcy Event in relation to the LICENSOR all licenses granted under this Agreement shall automatically include a right for IMMEDICA to Manufacture, or have Manufactured, the Product, including both the drug product and drug substance, and IMMEDICA is hereby authorized to contract with any party to the Manufacturing Agreements or any other Third Parties for the purposes of such Manufacture, provided always that this shall be without prejudice to the LICENSOR's right to receive royalties under Section 6.1.3. In the event that IMMEDICA undertakes Manufacture of the Product under this Section 7.8.5 (either itself or through an Affiliate or a Third Party) the LICENSOR will on request from IMMEDICA and at the LICENSOR'S own cost promptly conduct a technology transfer to IMMEDICA, its AFFILIATE or appointed Third Party supplier (as directed by IMMEDICA) to enable IMMEDICA to Manufacture or have Manufactured the Product. In addition if any Supply Failure results from a breach of any agreement between LICENSOR and a Third Party contract manufacturer of the Product IMMEDICA shall have the right to cure such breach on behalf of LICENSOR and LICENSOR shall reimburse IMMEDICA for all costs and, expenses incurred and compensation paid by IMMEDICA in connection with curing such breach.

7.9. **Defective Product.**

7.9.1. If a shipment of Product or any portion thereof is not in conformance with the Specifications, Applicable Law, GMP, the terms of the Quality Agreement or does not have specific activity required in accordance with the calculated therapeutic dose level when received by IMMEDICA or its agents at premises controlled by IMMEDICA, **("Defective Product")** then IMMEDICA shall have the right to reject such shipment of Product if the entire shipment is nonconforming, or the portion thereof that fails to so conform, as the case may be. IMMEDICA shall give notice to the LICENSOR of its rejection hereunder, as soon as practical after IMMEDICA's physical receipt of such shipment in premises controlled by IMMEDICA, specifying the grounds for such rejection. LICENSOR will not be responsible for any Defective Product as a result of transport delays or Product mishandling in each case caused by IMMEDICA or its agents. If LICENSOR has to replace Defective Product as a result of transport delays or Product mishandling caused by IMMEDICA or its agents, IMMEDICA shall reimburse LICENSOR for its fully burdened cost of Manufacture and supply of the replacement Product. Notwithstanding the foregoing, and solely until the expiration of the shelf-life for the applicable Product, in the event of any Defective Product which was not obvious on receipt of such shipment, IMMEDICA shall have [*] after becoming aware of such Defective Product to notify the LICENSOR.

7.9.2. IMMEDICA's grounds for rejection shall be conclusive unless the LICENSOR notifies IMMEDICA, within [*] of receipt by the LICENSOR of the notice of rejection, that it disagrees with such grounds. In the event of such a notice by the LICENSOR, representative samples of the Defective Product in question shall be submitted to a mutually acceptable independent laboratory or consultant (if not a laboratory analysis issue) for analysis or review, the costs of which shall be paid by the Party that is determined by the independent laboratory or consultant to have been incorrect in its determination of whether the applicable Product should be rejected.

7.9.3. In the event of any Defective Product, at IMMEDICA's sole discretion, the LICENSOR shall either, at the election of IMMEDICA: (i) replace such Defective Product, as soon as possible, and in any event within [*] after receipt of notice of rejection thereof, or (ii) reimburse IMMEDICA for any out-of-pocket costs incurred by IMMEDICA associated with the Defective Product (including all labeling and packaging costs, handling costs and transportation costs).

7.10. **Product Recall.**

7.10.1. If either Party becomes aware of information about distributed Product indicating that it may be non-conforming with respect to the Specifications, Applicable Law, GMP, or the terms of the Quality Agreement, or that there is potential adulteration, misbranding and/or any potential issues regarding safety or effectiveness with respect to the Product, it shall promptly serve written notice to that effect on the other Party. If such issue relates to a Defective Product, the LICENSOR shall initiate an investigation and assessment of such circumstances and shall provide IMMEDICA a written report of its findings and any proposed course of action to remedy such issue.

7.10.2. In the event: (i) any Regulatory Authority or other national government authority issues a request, directive or order that Product be recalled; (ii) a court of competent jurisdiction orders such a recall; or (iii) IMMEDICA reasonably determines that Product should be recalled, the Parties shall take all appropriate corrective actions, and shall cooperate in any governmental investigations surrounding the recall. In the event the LICENSOR reasonably determines that Product should be recalled, the LICENSOR shall provide notice to IMMEDICA including all relevant information that supports such determination. Upon receipt of any such notice, IMMEDICA shall promptly initiate a Product recall. IMMEDICA will have the responsibility for all communications with Regulatory Authorities in the Territory and customers regarding any recall of Product in the Field. The LICENSOR will give IMMEDICA any assistance that IMMEDICA may reasonably request to handle any recall.

7.10.3. In the event that such recall results from a Defective Product that was a Defective Product at the time of delivery of the Product, including the breach of the LICENSOR' s express warranties under Section 7.11, or the LICENSOR's negligence, recklessness or willful misconduct (a "LICENSOR Caused Recall"), the LICENSOR shall at IMMEDICA's option, promptly replace the quantity of Products that were recalled at no cost to IMMEDICA, or reimburse IMMEDICA for any out-of-pocket costs incurred by IMMEDICA associated with the Products that were recalled (including all labeling and packaging costs, handling costs and transportation costs). In the event that IMMEDICA elects to have the recalled Product replaced, the LICENSOR shall replace such Product as soon as possible. In the event that IMMEDICA elects to be reimbursed for out-of-pocket costs associated with the recalled Products, the LICENSOR shall reimburse IMMEDICA within [*] of receipt of request from IMMEDICA for reimbursement. In addition, the LICENSOR agrees that it shall be responsible for the expenses of any such LICENSOR Caused recall. For purposes of this Agreement, the expenses of the recall shall include the expenses of notification, and destruction or return of the recalled Product, and any costs associated with the distribution of the replacement Product. In the event that the recall was not a LICENSOR Caused Recall, then to the extent such recall affects Products in the Territory in the Field, the LICENSOR shall not be responsible for the expenses of the recall or for replacing or reimbursing the relevant Products.

7.11. **Supply Specific Representations and Warranties**

7.11.1. **Services.** The LICENSOR represents, warrants and covenants that: (a) it shall perform all Services in a professional manner, with due care and in accordance with industry standards; and (b) it shall perform all Services in accordance with: (i) Applicable Laws; (ii) GMP; and (iii) the terms and conditions of this Agreement.

7.11.2. **Product Warranties.** The LICENSOR warrants and covenants that all Product delivered to IMMEDICA pursuant to this Agreement shall conform with the Specificiations and the certificate of analysis, and shall be Manufactured in accordance with GMP and in compliance with Applicable Laws.

8. **RECORDS; AUDIT RIGHTS; INSPECTIONS**

8.1. **Records.**

8.1.1. **IMMEDICA's Records.** IMMEDICA shall maintain, and cause its Affiliates and Sublicensees to maintain, accurate financial books and records pertaining to the sale of the Product by IMMEDICA, its Affiliates and its Sublicensees, as applicable, including any and all calculations of the applicable Fees (collectively, **"Relevant Records").** IMMEDICA shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) [*] following the end of the Calendar Year to which such books and records pertain.

8.1.2. **The LICENSOR's Records.** The LICENSOR shall maintain, and cause its Affiliates and subcontractors to maintain, at the LICENSOR's cost, complete and accurate records related to the performance of LICENSOR's obligations under this Agreement, including in relation to all Services and Clinical Studies and any costs that LICENSOR incurs that are to be reimbursed by IMMEDICA (the **"LICENSOR Records").** LICENSOR shall provide IMMEDICA reasonable access to the LICENSOR Records upon the written request of IMMEDICA. Such access shall be requested in writing at least [*] in advance, and shall be conducted during the LICENSOR's normal business hours and otherwise in manner that minimizes any interference to the LICENSOR's business operations. The LICENSOR shall retain the LICENSOR Records, together with samples representing each batch of the Product delivered to IMMEDICA under this Agreement for at least [*] for LICENSOR Records and [*] after expiration of shelf-life for samples in each case from the shipment of the relevant batch of Product to IMMEDICA or such longer period as required by Applicable Laws.

8.2. **Audit Rights.**

8.2.1. **Audit Request.** LICENSOR shall have the right during the term of this Agreement and for [*] thereafter to engage, at its own expense, an independent auditor reasonably acceptable to IMMEDICA to examine the Relevant Records from time-to-time, but no more frequently than [*], as may be necessary to verify the amounts reported by IMMEDICA and IMMEDICA's compliance with the terms of this Agreement. Such audit shall be requested in writing at least [*] in advance, and shall be conducted during IMMEDICA's normal business hours and otherwise in manner that minimizes any interference to IMMEDICA's business operations. Such audits may not (i) be conducted for any Calendar Year ending more than [*] prior to the date of such request, (ii) be conducted more than [*] in any Calendar Year or (iii) be [*] for any Calendar Quarter.

8.2.2. **Audit Fees and Expenses.** Upon completion of any audit pursuant to Section 8.2.1, the independent auditor shall provide to the Parties a copy of its audit report disclosing any issues or discrepancies identified. LICENSOR shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment by IMMEDICA of more than [*] as to the period subject to the audit, IMMEDICA shall reimburse LICENSOR for the reasonable and documented fees and expenses charged by such independent auditor in connection with such audit.

8.2.3. **Payment of Deficiency.** If any audit establishes that IMMEDICA underpaid any amounts due to LICENSOR under this Agreement, then IMMEDICA shall pay LICENSOR any such deficiency, plus interest calculated in accordance with Section 6.1.5 from the date on which the payment was originally due, within [*] after receipt of written notice thereof. In the event such audit establishes that amounts were overpaid by IMMEDICA during such period, the amount of such overpayment plus interest calculated in accordance with Section 6.1.5 shall be credited against future amounts owed by IMMEDICA provided always that in the event an audit is conducted within the last [*] of the Term, such amount will be repaid to IMMEDICA.

8.2.4. **Confidential Financial Information.** The LICENSOR shall treat all financial information subject to review under this Section 8 as confidential and shall cause its independent auditor to retain all such financial information in confidence on terms no less restrictive than those applicable to the LICENSOR under Section 11 below.

8.3. **Inspections.**

8.3.1. Each Party shall promptly notify the other Party of any regulatory inspections that may impact the other Party's rights or obligations under this Agreement. The LICENSOR shall provide all reasonable co-operation to any inspection by any Regulatory Authority responsible for the approval of the Product in the Territory and shall facilitate reasonable access to the Facility and all LICENSOR Records. Unless not permitted by such Regulatory Authority, in the event of an inspection at the LICENSOR's premises or the Facility, IMMEDICA shall have the right (subject to Section 8.3.4 with respect to any Facility owned or controlled by a Third Party) to have a representative present during the portion of the inspection that involves the Product.

8.3.2. The LICENSOR shall, unless not permitted to do so by the Regulatory Authority, forward to IMMEDICA copies of any and all correspondence from and with any Regulatory Authority responsible for the approval of the Product in the Territory. To the extent the Product is implicated in regulatory inspection findings, the LICENSOR will provide a draft of the pertinent responses to IMMEDICA for review and comment prior to submission to the relevant Regulatory Authority responsible for the approval of the Product in the Territory; provided that the inspected entity is responsible for all responses to observations made by a Regulatory Authority and is not obligated to modify responses based upon IMMEDICA's comments.

8.3.3. . The LICENSOR shall promptly, and in any event within [*], after the LICENSOR becomes aware notify IMMEDICA in writing of any written observation, violation or deficiency noted, by a Regulatory Authority responsible for the approval of the Product in the Territory, following an inspection which related to or which may affect the Product or activities undertaken pursuant to this Agreement. The LICENSOR shall promptly rectify, and shall use reasonable efforts to cause its manufacturers to rectify, any such violation or deficiency at the LICENSOR's sole cost and expense.

8.3.4. Where any part of the Manufacturing process is undertaken by a Third Party on behalf of the LICENSOR, LICENSOR shall procure that such Third Party shall comply with the obligations set out in this Section 8.3. In respect of IMMEDICA' s right to have a representative present during an inspection pursuant to Section 8.3.1, LICENSOR's obligation will be to use its reasonable efforts to allow IMMEDICA to attend such inspection.

9. **INTELLECTUAL PROPERTY RIGHTS**

9.1. **Pre-existing** IP. Each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to or independent of this Agreement.

9.2. **Ownership of Inventions.** Inventorship of inventions shall be determined in accordance with the rules of inventorship under U.S. patent laws. As between the Parties, IMMEDICA (or its Affiliate) shall solely own all inventions made solely by IMMEDICA personnel, and the LICENSOR (or its Affiliate) shall solely own all inventions made solely by personnel of the LICENSOR. The Parties (or their respective Affiliates) shall jointly own all inventions made jointly by personnel of both IMMEDICA and the LICENSOR; provided that, subject to the rights and licenses granted under and the restrictions set forth in this Agreement, each Party may practice and exploit any such joint invention and/or any jointly owned Patent Rights to the extent such practice and exploitation does not infringe the Intellectual Property Rights of the other Party, including, without limitation, in connection with its development, manufacture and/or commercialization of products, without the consent of, or a duty of accounting to, the other Party, and each Party hereby waives any right it may have under applicable law to require such consent or accounting.

9.3. **License of Developed** IP. Any Patent Rights that are conceived, developed or reduced to practice by or on behalf of IMMEDICA as a direct result of the performance of its activities under this Agreement are, to the extent they are Controlled by IMMEDICA **("Developed IP**"), hereby licensed to the LICENSOR on a non-exclusive, fully paid-up basis, for the sole and limited purpose of the Development, Manufacture, and Commercialization of the Product in all territories and countries of the world other than the Territory (provided that after any termination of this Agreement, the foregoing license shall be worldwide).

9.4. **Recording of License.** If either Party considers it advisable to record IMMEDICA as a licensee or "registered user" of any of the Licensed Technology under local law, the other Party shall do all such acts and sign or have signed all such documents as are reasonably proper and necessary to secure such recordation and for any changes thereof in the future. In such event, the relevant Party is responsible for recording this Agreement or a document reflecting this Agreement's contents with any applicable governmental authority and for all associated recordation fees and related costs and expenses. Upon termination of IMMEDICA's rights under this Agreement, either Party may at any time thereafter apply for cancellation of the record of IMMEDICA as a licensee (in the case of LICENSOR, upon written notice to IMMEDICA).

9.5. **Patent and Trademark Prosecution.**

9.5.1. **Patent and Trademark Prosecution and Maintenance.** Subject to IMMEDICA's rights set forth in Section 9.5.3 and Section 9.5.4, the LICENSOR will be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions and the like), defending and maintaining the Licensed Patents and all Product Trademarks in all countries in the Territory in LICENSOR's name at LICENSOR's own cost and expense.

9.5.2. Assistance.

(a) The LICENSOR shall inform IMMEDICA as to the prosecution and maintenance and defence of the Licensed Patents and Product Trademarks in the Territory prior to any deadline, submission to or action with any patent or trademark office, and shall furnish to IMMEDICA copies of all relevant drafts and documents of such Licensed Patents or relating to the Product trademarks reasonably in advance of such consultation. The LICENSOR shall provide to IMMEDICA copies of all patent office and trademark submissions and correspondence relevant to such Licensed Patents and Product Trademarks within a reasonable amount of time following submission or receipt thereof by the LICENSOR. The LICENSOR shall consider in good faith any reasonable and timely comments provided by IMMEDICA in connection with the prosecution and maintenance and defence of such Licensed Patents and Product Trademarks. LICENSOR will discuss and agree with IMMEDICA any proposal to opt-in or opt-out of the proposed Unified Patent Court system should that come into effect or to designate a Licensed Patent as a Unitary Patent.

(b) IMMEDICA will provide reasonable assistance to LICENSOR, at LICENSOR's expense, in connection with the filing, prosecution and maintenance and defence of such Licensed Patents and Product Trademarks, where such assistance shall include providing access to relevant persons and executing all documentation reasonably requested by LICENSOR.

(c) As reasonably requested by LICENSOR in writing and at LICENSOR's expense, IMMEDICA shall cooperate in obtaining patent term restoration (under, but not limited to, the Drug Price Competition and Patent Term Restoration Act), supplementary protection certificates or their equivalents, and patent term extensions with respect to the Licensed Patents in Europe.

9.5.3. **Failure to Prosecute or Maintain.** In the event LICENSOR elects to forgo filing, prosecution or maintenance or defence of any of the Licensed Patents or Product Trademarks in any country in the Territory, LICENSOR shall promptly notify IMMEDICA of such election, but in any event at least [*] prior to any filing or payment due date, or any other due date that requires action **("Election Notice").** Upon receipt of an Election Notice, IMMEDICA shall be entitled, upon written notice to LICENSOR, at its sole discretion and expense, to file or to continue the prosecution or maintenance of such Licensed Patent or Product Trademarks in such country in LICENSOR's name using counsel of its own choice and at its own expense, provided that IMMEDICA shall keep the LICENSOR reasonably informed as to the material actions taken with regard to the prosecution and maintenance and defence of such Licensed Patents and Product Trademarks in the Territory. The LICENSOR shall cooperate with IMMEDICA to transfer the prosecution and maintenance of such Licensed Patent and Product Trademarks, together with all relevant documentation and the file wrapper, to IMMEDICA. If requested by IMMEDICA, the LICENSOR shall ensure that the LICENSOR's patent or trademark attorney liaises with IMMEDICA's patent attorney to ensure a smooth and complete transfer of prosecution and maintenance obligations.

9.5.4. **Trademarks.**

The Parties recognize the importance of having a coordinated global approach to the use of trademarks in relation to the Product and to that end and to the extent reasonably possible in accordance with Appl: able Law agree to use the same trademarks on Product inside the Territory and outside the Territory. LICENSOR in consultation with IMMEDICA, shall be responsible for the creation, filing, registration, and prosecution and maintenance of the Product Trademarks in the Territory. LICENSOR, in consultation with IMMEDICA, shall undertake the searching and clearance of all potential Product Trademarks within the Territory as soon as reasonably possible following the Effective Date. If LICENSOR fails to apply for trademarks for the Product within the Territory reasonably in advance of IMMEDICA'S intended launch of the Product in the Territory IMMEDICA shall be free to do so and shall own all resulting trademarks. IMMEDICA shall use the Product Trademarks registered by LICENSOR in connection with the Product in the Field within the Territory.

10. **INFRINGEMENT; MISAPPROPRIATION**

10.1. **Notification.** Each Party will promptly notify the other Party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Technology or any Product Trademark in the Territory of which it becomes aware **("Third Party Infringement").**

10.2. **Infringement Action.**

10.2.1. Right of First Enforcement.

(a) LICENSOR shall have the first right (but not the obligation), at its own expense, to control enforcement of the Licensed Technology and Product Trademarks against any Third Party Infringement (each an **"Enforcement Action"),** after having conferred with IMMEDICA. LICENSOR shall keep IMMEDICA reasonably updated with regard to the progress of any such Enforcement Action that it takes. LICENSOR shall give IMMEDICA timely notice of any proposed settlement of any such action instituted by LICENSOR and shall not enter into any settlement that would: (i) admit the liability of IMMEDICA or its Affiliates, or (ii) materially affect the scope of validity of any Licensed Patent or Trademark, or (iii) materially adversely effect the Commercialization of the Product in the Territory, in each case with respect to the foregoing clauses (i)-(iii), without the prior written consent of IMMEDICA, which consent shall not be unreasonably withheld, conditioned or delayed.

(b) If LICENSOR does not initiate proceedings within [*] from the date of IMMEDICA's request that LICENSOR initiate such proceedings, then IMMEDICA shall have the right but shall not be obliged, upon prior written notice to LICENSOR, to initiate infringement proceedings or take other action it believes appropriate against such Third Party Infringement at its own expense.

10.2.2. Assistance. At the request and sole cost and expense of the Party controlling an Enforcement Action, the other Party shall provide reasonable assistance in connection therewith. If one Party brings any suit, action or proceeding under this Section 10.2, the other Party agrees to be joined as party plaintiff if reasonably necessary to prosecute the suit, action or proceeding and to give the first Party authority to file, prosecute and control the suit, action or proceeding; provided however that such non- controlling Party shall have the right, at its own expense, to be represented in any such action in which it is a party by independent counsel of its own choice.

10.2.3. Recoveries. Any recoveries resulting from an action relating to a claim of Third Party Infringement shall first be applied against payment of each Party's costs and expenses incurred in connection therewith. Any remaining recoveries shall be retained by IMMEDICA; provided that LICENSOR shall be entitled to a Royalty on such remaining recoveries at the applicable rate set forth in Section 6.1 as if the amount of such remaining recoveries were Net Sales of IMMEDICA in the Calendar Year in which the recoveries were received by IMMEDICA. Notwithstanding the foregoing, any recoveries resulting from an action relating to a claim of Third Party Infringement shall not be included in the calculation of any commercial milestones under Section 1.2 of Schedule B.

10.2.4. Third Party Infringement Claims. If the Development, Manufacture or Commercialization of any Product in any country of the Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent or other intellectual property infringement against the LICENSOR or IMMEDICA (or their respective Affiliates, or Sublicensees) (collectively, **"Infringement Actions"),** such Party shall promptly notify the other Party hereto in writing. IMMEDICA shall be indemnified in respect of any such Infringement Action in accordance with Section 13.1 and LICENSOR shall have the right to direct and control the defense thereof, at its own expense with counsel of its choice in accordance with Section 13.3. LICENSOR shall keep IMMEDICA reasonably informed of all material developments in connection with any such Infringement Action.

11. **CONFIDENTIALITY**

11.1. **Definition. "Confidential Information"** means the terms and provisions of this Agreement and other proprietary information and data of a financial, commercial or technical nature that the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether disclosed in writing, orally or otherwise. The terms of this Agreement shall be considered the Confidential Information of both Parties.

11.2. **Obligations.** During the term of this Agreement, and for [*] thereafter (or, in the case of Confidential Information constituting a trade secret, for such longer period of time that the Confidential Information remains a trade secret under Applicable Law), the receiving Party will protect all Confidential Information against unauthorized access, use or disclosure to Third Parties with the same degree of care as the receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The receiving Party may disclose the Confidential Information to its Affiliates, and their respective directors, officers, employees, subcontractors, consultants, attorneys, and accountants, banks (to the extent required by applicable borrowing documentation) and investors who hold a majority of the voting equity of a Party (collectively, **"Recipients")** who (a) have a need-to-know such information for purposes related to this Agreement, (b) are informed of the confidential nature of the Confidential Information and the receiving Party' s obligations hereunder, and (c) are bound by written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

11.3. **Exceptions.**

11.3.1. The obligations under this Section 11 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party;

(c) is disclosed to the receiving Party on a nonconfidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

11.3.2. Notwithstanding anything herein to the contrary, the receiving Party may disclose Confidential Information to the extent such disclosure is required under Applicable Laws or a court order or other governmental order, provided that the receiving Party: (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure and (c) if the disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel. Confidential Information disclosed pursuant to this Section 11 shall remain subject to the restrictions set forth herein for all other purposes.

11.3.3. In the event that LICENSOR wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, LICENSOR may disclose to a Third Party such Confidential Information of IMMEDICA as LICENSOR deems reasonably necessary in connection with any such proposed assignment, provided that LICENSOR shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

11.3.4. IMMEDICA may disclose Confidential Information of the LICENSOR to the extent such disclosure is reasonably necessary in the following instances:

(a) with LICENSOR' s written consent (such consent not to be unreasonably withheld, conditioned or delayed), filing for, prosecuting or enforcing Licensed Patents in accordance with this Agreement;

(b) in Regulatory Filings or otherwise in seeking, obtaining and maintaining Regulatory Approvals (including complying with the requirements of Regulatory Authorities with respect to filing for, obtaining and maintaining such Regulatory Approvals);

(c) the Development and/or Commercialization of the Product in the Territory, provided, that any Third Party to whom IMMEDICA discloses Confidential Information pursuant to this clause (c) (i) are informed of the confidential nature of the Confidential Information and IMMEDICA's obligations hereunder and (ii) are bound by written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement; and

(d) disclosing to actual or *bona fide* potential Sublicensees or subcontractors in connection with the exercise of its rights under this Agreement or related activities, provided, that such Sublicensees and subcontractors (i) are informed of the confidential nature of the Confidential Information and IMMEDICA's obligations hereunder and (ii) are bound by written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

11.3.5. Each Party shall be responsible for any breaches of confidentiality by any of its Affiliates, subcontractors, Sublicensees, Recipients, advisors and Third Parties to whom it discloses Confidential Information pursuant to Section 11.

11.3.6. **Confidential Disclosure of Terms.** Each Party agrees not to disclose to any Third Party the existence and/or terms of this Agreement without the prior written consent of the other Party hereto, except as permitted under this Section 11, and notwithstanding the foregoing, each Party may disclose the existence and/or terms of this Agreement to its advisors (including financial advisors, attorneys and accountants), potential and existing investors, collaboration partners or acquirers, and others on a reasonable need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof.

11.4. **Right to Injunctive Relief.** The Parties agree that breaches of this Section 11 may cause irreparable harm to the non-breaching Party and shall entitle the non-breaching Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action, and each Party hereby waives any requirement to post a bond or other security or prove actual damages or that monetary damages will not afford an adequate remedy.

11.5. **Ongoing Obligation for Confidentiality.** Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one copy which may be retained in its confidential files for archive purposes.

11.6. **Data Protection Regulations.** Each Party will collect, use, and disclose information governed by this Agreement in compliance with all applicable privacy and data protection laws, rules, and regulations and in accordance with the terms of a data sharing agreement that will be agreed by the Parties acting reasonably and in good faith within [*] of the Effective Date. The Parties shall enter into any additional agreements regarding the collection, use, processing or disclosure of such information as mandated by such data protection laws, rules and regulations. The Parties shall notify each other promptly of any unauthorized uses or disclosures of such information of which they become aware.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1. **Representations and Warranties by Each Party.** Each Party represents and warrants to the other Party as of the Effective Date that:

12.1.1. it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

12.1.2. it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

12.1.3. this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

12.1.4. all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

12.1.5. the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

12.2. **Representations and Warranties by LICENSOR.** LICENSOR represents and warrants to IMMEDICA as of the Effective Date that:

12.2.1. there is no actual alleged or threatened claim that has been notified in writing to the Licensor or its Affiliates or, to its Knowledge, any pending or possible claim that the Development, Manufacture or Commercialization of the Product within the Territory infringes, misappropriates or otherwise violates the Intellectual Property Rights of a Third Party. As used in this Section 12.2, **"Knowledge"** means knowledge of the officers of LICENSOR, and is not meant to require or imply that any particular inquiry or investigation has been undertaken including, without limitation, obtaining any type of search (independent of that performed by the actual governmental authority during the normal course of patent prosecution, as applicable, in a jurisdiction) or opinion of counsel, provided that it shall include the knowledge that would be obtained from reasonable inquiries that a person in that position would normally be expected to have made;

12.2.2. there is no actual, pending, alleged or threatened claim by LICENSOR or its Affiliate alleging that a Third Party is or was infringing, misappropriating or otherwise violating the Licensed Technology within the Territory;

12.2.3. to its Knowledge, the practice of the Licensed Patents or the Licensed Know-How and the Development, Manufacture and/or Commercialization of any Product does not infringe, violate or misappropriate the Intellectual Property Rights of any Third Party;

12.2.4. Schedule A sets forth a true and complete list of all Licensed Patents Controlled by the LICENSOR or its Affiliates as of the Effective Date that Cover the Product, and the LICENSOR has the full right and authority to grant to IMMEDICA the right to use, sell, offer to sell, import and sublicense the Patent Rights in the Territory described in Schedule A, and to enforce such Patent Rights in accordance with Section 10 above;

12.2.5. the LICENSOR has not previously granted and will not grant any right, license or interest in or to a Product, Licensed Know-How and/or Licensed Patents, or any portion thereof, that is in conflict with, limits or derogates from the rights or licenses granted to IMMEDICA under this Agreement;

12.2.6. the Licensed Patents and the Licensed Know-How are free and clear of all liens, claims, security interests or other encumbrances of any kind and during the term of this Agreement, the LICENSOR shall not permit the Licensed Patents or the Licensed Know-How to become encumbered by any liens, claims, security interests or other encumbrances, in each case of the foregoing that could diminish IMMEDICA's rights or licenses with respect to Licensed Patent Rights;

12.2.7. the LICENSOR has not knowingly withheld any Licensed Know-How that is reasonably relevant for IMMEDICA's conduct of activities under this Agreement and, to the LICENSOR'S Knowledge, all Licensed Know-How provided to IMMEDICA is free from any material inaccuracies;

12.2.8. the LICENSOR has disclosed to IMMEDICA all material information relating to the safety and efficacy of the Product known to it or its Affiliates;

12.2.9. the LICENSOR has complied with all Applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Licensed Patents and, to the LICENSOR's Knowledge, none of the issued Licensed Patents are invalid or unenforceable;

12.2.10. the LICENSOR has conducted, and its contractors and consultants have conducted, all its Development activities relating to the Product, including the Phase III Clinical Trial, in accordance with Applicable Laws including, as applicable, GLP and GCP;

12.2.11. neither the LICENSOR nor any of its Affiliates are, or have been, debarred or disqualified by any Regulatory Authority; and none of the LICENSOR or any of its Affiliates' employees or contractors who were involved in the Development, Manufacture or Commercialization of the Product are, or have been, debarred or disqualified by any Regulatory Authority;

12.2.12. the materials and documents provided to IMMEDICA in the course of IMMEDICA's due diligence preceding execution of this Agreement were free from any material inaccuracies;

12.2.13. the LICENSOR has made available to IMMEDICA all material information in the LICENSOR's or its Affiliate's control relating to the Development and Manufacture of the Products as conducted by or on behalf of the LICENSOR and its Affiliates prior to the Effective Date, including complete and correct copies of the following: adverse event reports; clinical study reports and material study data; and Regulatory Authority inspection reports, notices of adverse findings, warning letters, Regulatory Filings and other material correspondence with Regulatory Authorities;

12.2.14. neither the LICENSOR nor any of its employees have been "debarred" by the FDA or the EMA, or subject to a similar sanction from another Regulatory Authority, nor have debarment proceedings against the LICENSOR or any of its employees been commenced. The LICENSOR will promptly notify IMMEDICA in writing if any such proceedings have commenced or if the LICENSOR or any of its employees are debarred by the FDA or the EMA or any other Regulatory Agency;

12.2.15. it shall not hire or retain as an officer or employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the FDCA. If at any time this representation and warranty is no longer accurate, the LICENSOR shall immediately notify IMMEDICA of such fact;

12.2.16. all personal data and biological specimens collected from or disclosed by human subjects in Clinical Studies of the Products have been collected, used, processed and disclosed in compliance with Applicable Laws;

12.2.17. to the Knowledge of the LICENSOR, the Phase III Clinical Trial will, if it meets its primary endpoints, produce sufficient clinical data to support an application for Regulatory Approval of the Product in AML with the EMA without the need for additional Clinical Studies, provided that this representation and warranty shall not be taken as a representation and or warranty that the Phase III Clinical Trial will meet its primary endpoints or that any application for Regulatory Approval for the Product will be successful;

12.2.18. the Existing Agreements are in full force and effect and the Licensor has complied in all material respects with each of its obligations the Existing Agreements in a timely manner, and has paid all payments owed by the LICENSOR under the Existing Agreements in full and on time;

12.2.19. the LICENSOR is not in breach of any material term of the Manufacturing Agreements and, to its Knowledge, no counterparty to the Manufacturing Agreements is in breach of any material term of the Manufacturing Agreements; and

12.2.20. to its Knowledge, the Facility meets all requirements under Applicable Law, including under GMP, for the Manufacture of the Product for Commercialization in the European Union.

12.3. **Representations and Warranties by IMMEDICA.** IMMEDICA represents and warrants to LICENSOR as of the Effective Date that:

12.3.1. to its Knowledge, the practice of the Licensed Patents or the Licensed Know-How and the Development, Manufacture and/or Commercialization of any Product within the Territory does not infringe, violate or misappropriate the Intellectual Property Rights of any Third Party. As used in this Section 12.3, **"Knowledge"** means knowledge of the officers of IMMEDICA, and is not meant to require or imply that any particular inquiry or investigation has been undertaken including, without limitation, obtaining any type of search (independent of that performed by the actual governmental authority during the normal course of patent prosecution, as applicable, in a jurisdiction) or opinion of counsel, provided that it shall include the knowledge that would be obtained from reasonable inquiries that a person in that position would normally be expected to have made; and

12.3.2. to its Knowledge, the granted patents within the Licensed Patents are valid and enforceable.

12.4. **No Other Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS SECTION 12, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON- INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

12.5. **Maintenance of the Existing Agreements.**

12.5.1. On an Existing Agreement-by-Existing Agreement basis, the LICENSOR shall ensure that such Existing Agreement is not terminated, revoked or allowed to expire during the term of this Agreement for any reason attributable to the LICENSOR. The LICENSOR shall:

(a) not terminate such Existing Agreement without first obtaining IMMEDICA's express written consent to such termination;

(b) ensure that it complies, at all times, with each of its obligations under such Existing Agreement in a timely manner, and shall ensure that all payments owed by the LICENSOR under such Existing Agreement are paid in full and on time; and

(c) not agree or consent to any amendment, supplement, or other modification (including termination) to such Existing Agreement which could adversely affect IMMEDICA's rights under this Agreement without IMMEDICA's prior written consent.

12.6. **Maintenance of the Manufacturing Agreements.**

12.6.1. On a Manufacturing Agreement-by-Manufacturing Agreement basis, from and after the Effective Date, the LICENSOR shall ensure that such Manufacturing Agreement is not terminated, revoked or allowed to expire during the term of this Agreement for any reason attributable to the LICENSOR. The LICENSOR shall:

(a) not terminate such Manufacturing Agreement without first obtaining IMMEDICA's express written consent to such termination (such consent not to be unreasonably withheld, conditioned or delayed);

(b) ensure that it complies, at all times, with each of its obligations under such Manufacturing Agreement in a timely manner, and shall ensure that all payments owed by the LICENSOR under such Manufacturing Agreement are paid in full and on time; and

(c) not agree or consent to any amendment, supplement, or other modification (including termination) to such Manufacturing Agreement which could adversely affect IMMEDICA or the supply of Product under this Agreement without IMMEDICA's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed).

Notwithstanding the foregoing, LICENSOR shall have the right without needing the consent of IMMEDICA to utilize other manufacturers provided that LICENSOR shall be responsible for any studies necessary to demonstrate the equivalence of the Product manufactured at such other manufacturers and the terms of any agreements with such manufacturers, to the extent such terms impact IMMEDICA's rights or the LICENSOR's ability to supply Product under the terms of this Agreement, are no less favourable in any material respect than the terms of the Manufacturing Agreements. LICENSOR shall continue to supply the Product to IMMEDICA without amendment until such time as any change or variation to a Regulatory Approval that is required as a result of such use of alternative manufacturers is approved by the applicable Regulatory Authority. If the LICENSOR proposes to enter into any new agreements with Third Parties relating to the Manufacture of the Product it shall notify IMMEDICA in writing and such proposal shall be discussed at the JSC. LICENSOR shall keep IMMEDICA reasonably informed with regard to the progress of any discussions with any such Third Party and will provide to IMMEDICA a copy of any agreement entered into with such a Third Party.

12.6.2. The LICENSOR covenants that promptly and in any event within [*] of the Effective Date, subject to Section 12.6.l(c), LICENSOR shall put in place an amendment to each of the Manufacturing Agreements to cover clinical and commercial supply of the Product to IMMEDICA in the Territory as contemplated by this Agreement.

13. **INDEMNIFICATION**

13.1. **Indemnification by LICENSOR.** The LICENSOR agrees to indemnify, hold harmless and defend IMMEDICA, its Affiliates and Sublicensees and their respective officers, directors, employees, contractors, agents and assigns (collectively the **"IMMEDICA Indemnitees"),** from and against any Claims arising or resulting from (a) the Development of a Product, including the performance of any Clinical Studies by the LICENSOR, its Affiliates, or respective subcontractors, (b) any breach by the LICENSOR of any representation, warranty or covenant as set forth in this Agreement, (c) any Claim or allegation that the Development, Manufacture and Commercialization of the Product in the Territory infringes the Intellectual Property Rights of a Third Party (including any Infringement Action) or (d) the negligence, recklessness or wrongful intentional acts or omissions of any Licensor Indemnitees; except to the extent in each case (a) to (c) such Claims result from the breach of this Agreement by IMMEDICA, or the negligence, recklessness or wrongful intentional acts or omissions of any IMMEDICA Indemnitees.

13.2. Indemnification by IMMEDICA. IMMEDICA agrees to indemnify, hold harmless and defend LICENSOR and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns (collectively, **"Licensor Indemnitees"),** from and against any Claims arising or resulting from: (a) the Development of a Product by IMMEDICA, its Affiliates, its Sublicensees or their respective subcontractors, (b) the Commercialization of a Product by IMMEDICA, its Affiliates, its Sublicensees, or their respective subcontractors, (c) the negligence, recklessness or wrongful intentional acts or omissions of IMMEDICA, its Affiliates, its Sublicensees or their respective subcontractors, or (d) breach by IMMEDICA of any representation, warranty or covenant as set forth in this Agreement; except to the extent in each case (a) to (d), such Claims result from the breach of this Agreement by the LICENSOR, or the negligence, recklessness or wrongful intentional acts or omissions of any Licensor Indemnitees.

13.3. Indemnification Procedure. In connection with any Claim for which a Party (the **"Indemnitee")** seeks indemnification from the other Party (the **"Indemnitor")** pursuant to this Agreement, the Indemnitee shall: (a) give the Indemnitor prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve the Indemnitor from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnitor, at the Indemnitor's expense, in connection with the defense and settlement of the Claim; and (c) permit the Indemnitor to control the defense and settlement of the Claim; provided, however, that the Indemnitor may not settle the Claim without the Indemnitee's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, in the event such settlement materially adversely impacts the Indemnitee's rights or obligations. Further, the Indemnitee shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

13.4. Third Party Intellectual Property. If a Third Party notifies IMMEDICA, its Affiliates, distributors or Sublicensees that Intellectual Property Rights owned or controlled by such Third Party cover the use or sale of the Product in the Territory **("Third Party IP Rights"),** then IMMEDICA shall, upon becoming aware of such notice, promptly notify LICENSOR **("Third Party Notice")** and give LICENSOR the exclusive right to negotiate with such Third Party. If LICENSOR obtains a license or other right from such Third Party for such Third Party IP Rights, LICENSOR shall ensure that LICENSOR has the right to sublicense to IMMEDICA under this Agreement, and LICENSOR shall bear all costs and expenses of such license (including milestones and royalties). In any event, from the date of LICENSOR's receipt of the Third Party Notice, LICENSOR shall indemnify, hold harmless and defend the IMMEDICA Indemnitees from and against any Claims from such Third Party with respect to the infringement of the Third Party IP Rights from the use or sale of the Product in the Territory.

14. **LIMITATION OF LIABILITY**

14.1. Consequential Damages Waiver. EXCEPT FOR A BREACH OF SECTION 11, NEITHER PARTY SHALL BE LIABLE FOR ANY LOSS OF GOODWILL, REPUTATION, BUSINESS, REVENUES, INDIRECT PROFITS, ANTICIPATED PROFITS, CONTRACTS, OR OPPORTUNITIES (REGARDLESS OF HOW THESE ARE CLASSIFIED AS DAMAGES) OR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

NOTHING IN THIS AGREEMENT EXCLUDES OR LIMITS ANY LIABILITY FOR DEATH OR PERSONAL INJURY CAUSED BY NEGLIGENCE, FOR FRAUD OR FOR ANY OTHER LIABILITY WHICH CANNOT LEGALLY BE EXCLUDED OR LIMITED.

NOTWITHSTANDING THE FOREGOING, THE LIMITATIONS SET FORTH IN THIS SECTION 14.1 SHALL NOT LIMIT AN INDEMNITOR' S LIABILITY FOR DAMAGES AWARDED TO ANY THIRD PARTY IN CONNECTION WITH ANY CLAIM FOR WHICH A PARTY IS ENTITLED TO INDEMNIFICATION UNDER SECTION 13.

NOTWITHSTANDING ANY OTHER PROVISION IN THIS SECTION 14.1, THE LICENSOR SHALL NOT BE LIABLE FOR ANY LOSS OF PROFIT CLAIMED BY IMMEDICA TO THE EXTENT SUCH LOSS OF PROFIT ARISES FROM AN ACT OR OMISSION OF A THIRD PARTY SUPPLIER TO LICENSOR AND THE TERMS OF THE CONTRACT BETWEEN LICENSOR AND SUCH THIRD PARTY SUPPLIER EXCLUDES OR LIMITS THE RECOVERY OF SUCH LOSS OF PROFIT.

A PARTY'S AGGREGATE LIABILITY FOR ANY AND ALL CLAIMS BY THE OTHER PARTY FOR ANY DIRECT LOSS OF PROFIT ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT SHALL NOT EXCEED

[*] OF THE TOTAL OF ANY SUMS WHICH HAVE BEEN PAID BY IMMEDICA TO LICENSOR UNDER THIS AGREEMENT EXCLUDING, EXCEPT IN THE CASE OF AN INTENTIONAL BREACH BY LICENSOR WITHIN [*] OF THE EFFECTIVE DATE, THE UPFRONT PAYMENT REFERRED TO IN SECTION 6.1.1,

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A SUM EQUIVALENT TO [*] OF THE TOTAL VALUE OF NET PROFIT ON SALES OF THE PRODUCT ACHIEVED BY IMMEDICA IN THE [*] PRIOR TO THE DATE ON WHICH THE MATTER GIVING RISE TO THE CLAIM FIRST AROSE.

15. **TERM; TERMINATION**

15.1. **Term.** The term of this Agreement shall commence as of the Effective Date and shall continue until terminated in accordance with this Section 15.

15.2. **Termination for Cause.** Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party is in material breach of this Agreement and fails to cure such breach within [*] of receiving notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such [*] period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed [*]. Any termination by a Party under this Section 15.2 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party.

15.3. **Termination for a Bankruptcy Event.** Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. **"Bankruptcy Event"** means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the **"Bankruptcy Code"),** where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [*] after they are instituted, (b) the insolvency of a Party or making of an assignment for the benefit of creditors, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, or (d) appointment of a receiver for all or substantially all of a Party's assets (each an **"Insolvency Event").** All rights and licenses now or hereafter granted by the LICENSOR to IMMEDICA under or pursuant to this Agreement, including, for the avoidance of doubt, the license granted to IMMEDICA pursuant to Section 2.1, are, for all purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in the Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to LICENSOR, the LICENSOR agrees that IMMEDICA, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Without limiting the generality of the foregoing, the LICENSOR and IMMEDICA intend and agree that any sale of the LICENSOR's assets under Section 363 of the Bankruptcy Code shall be subject to IMMEDICA's rights under Section 365(n), that IMMEDICA cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of IMMEDICA's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of IMMEDICA.

15.4. **Termination for Challenge to Licensed Technology.** LICENSOR shall have the right to terminate this Agreement at any time after the Effective Date on [*] written notice in its entirety or on a country-by-country basis in the event IMMEDICA or any of its Affiliates or Sublicensees contests or challenges, or supports or assists any Third Party to contest or challenge, in any patent office, court, regulatory agency or other forum, the validity, enforceability or scope of, any of the Licensed Patents (a **"Patent Challenge");** provided that if a Licensed Patent is asserted against IMMEDICA, or any of its Affiliates or Sublicensees in an infringement action or other legal proceeding with respect to activities outside the licenses granted herein, or any sublicense granted hereunder, then any claim or action taken in defense of such assertion shall not be deemed a Patent Challenge. Any termination for Patent Challenge shall be subject to the notification and cure procedure set out in Section 15.2, including a right for IMMEDICA to withdraw or rectify the Patent Challenge during the cure period in which case LICENSOR shall have no right to terminate this Agreement at the end of the cure period if the Patent Challenge has been so withdrawn or rectified. Any attempt to cure a breach of this Section 15.4 requires IMMEDICA to reimburse LICENSOR for any and all expenses and costs, including all legal fees, incurred as a result of the Patent Challenge.

15.5. **Termination by IMMEDICA.** IMMEDICA shall have the right to terminate this Agreement in its entirety, or on a country-by-country basis, without cause, and for any or no reason on not less than [*] prior written notice to the LICENSOR.

15.6. **Effect of Termination or Expiration.**

15.6.1. Upon termination or expiration of this Agreement, IMMEDICA shall pay to LICENSOR all amounts due to LICENSOR as of the effective date of termination or expiration within [*] following the effective date of termination or expiration.

15.6.2. Upon termination of this Agreement, IMMEDICA shall have the right to sell its remaining inventory of Product following the termination of this Agreement so long as IMMEDICA has fully paid, and continues to fully pay when due, any and all Royalties owed to LICENSOR, and IMMEDICA otherwise is not in material breach of this Agreement.

15.6.3. Upon termination of this Agreement but not expiration, all licenses granted by one Party to the other Party shall terminate. For clarity, termination of the licenses granted by LICENSOR to IMMEDICA shall terminate all sublicenses granted by IMMEDICA hereunder.

15.6.4. With the exception of termination of this Agreement by IMMEDICA pursuant to Section 15.2 or 15.3, upon termination of this Agreement:

(a) To the extent permitted by applicable Regulatory Authorities, IMMEDICA shall, at IMMEDICA's cost: (i) transfer, or cause to be transferred, to LICENSOR all Regulatory Filings and Regulatory Approvals held by IMMEDICA, its Affiliates and its Sublicensees with respect to the Product, and (ii) to the extent subsection (i) is not permitted by the applicable Regulatory Authority, permit LICENSOR, or cause its Affiliates and its Sublicensees to permit LICENSOR to cross-reference and rely upon any Regulatory Approvals and Regulatory Filings owned by IMMEDICA, its Affiliates and its Sublicensees with respect to the Product.

15.7. **Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 1, 5.4, 7.10, 8.1, 8.2, 8.3, 9.1, 9.2, 9.3, 9.4, 11, 13, 15.6, 18 and 19 shall survive expiration or termination of this Agreement.

16. **PUBLICITY**

16.1. **Publicity.**

16.1.1. Subject to IMMEDICA's rights pursuant to Section 2.1.2, neither Party (nor any of its Affiliates or agents) shall use the trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance.

16.1.2. The Parties have mutually approved a press release attached hereto as Schedule D with respect to this Agreement. Each Party agrees not to issue any other press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party, provided however, that (i) neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law or the rules of any recognized stock exchange so long as the disclosing Party provides the other Party prior written notice to the extent practicable and only discloses information to the extent required, in the reasonable opinion of such Party's legal counsel, by Applicable Law or the rules of any recognized stock exchange, (ii) once the press release set out in Schedule D has been released, each Party may disclose the information contained in such press release without further consent, and (iii) IMMEDICA shall have the right to publicly disclose without the LICENSOR's prior written consent: (A) the achievement of any milestone under this Agreement ; or (B) any information (other than Confidential Information of Licensor) relating to the Development or Commercialization of any Products in the Territory.

17. **INSURANCE**

17.1. **Insurance Requirements.** The Parties will each maintain during the term of this Agreement and for [*] after termination or expiration of this Agreement, commercial general liability insurance from a minimum [*] rated insurance company, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of [*] per occurrence and [*] in the aggregate. Each Party has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on a Party's liability hereunder.

17.2. **Policy Notification.** On request, each Party shall provide the other Party with certified copies of such policies or original certificates of insurance evidencing such insurance: (a) prior to execution by both Parties of this Agreement, and (b) prior to expiration of any such coverage.

18. **DISPUTE RESOLUTION**

18.1. **General.** Except for disputes for which injunctive or other equitable relief is sought to prevent the unauthorized use or disclosure of proprietary materials or information or prevent the infringement or misappropriation of a Party's Intellectual Property Rights, the following procedures shall be used to resolve any dispute arising out of or in connection with this Agreement.

18.2. **Meeting.** Promptly after the written request of either Party, each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute arising out of or in connection with this Agreement. If the designated representatives do not resolve the dispute within [*] of such request, then an executive officer of each Party shall meet in person or by telephone to review and attempt to resolve the dispute in good faith. The executive officers shall have [*] to attempt to resolve the dispute.

18.3. **Arbitration.**

18.3.1. Any disputes arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination that are not otherwise resolved by the Parties in accordance with Section 18.2 shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The Parties agree, pursuant to Article 30(2)(b) of said Rules that the Expedited Procedure Rules shall apply irrespective of the amount in dispute. The language of the arbitration shall be English. The number of arbitrators shall be one; provided that if the Parties fail to nominate a mutually acceptable sole arbitrator within [*] from the date when the Request for Arbitration has been received by the other Party, the number of arbitrators shall be three. The seat, or legal place, of arbitration shall be London, England.

18.3.2. The arbitrator(s) shall not be an officer or employee of either Party. The cost of the arbitration, including the fees and expenses of the arbitrator(s), will be shared equally by the Parties. The prevailing Party shall be entitled to recover from the losing Party the prevailing Party's arbitration costs, including reasonable attorneys' fees and costs and the fees and expenses of the arbitrator(s). The arbitration award will be presented to the Parties in writing, and upon the request of either Party, will include findings fact and conclusions of law. The award may be confirmed and enforced in any court of competent jurisdiction.

18.3.3. If a Party asserted to be in breach under Section 15.2 above disputes the asserted breach, this Agreement shall not be terminated and the licenses herein shall not be affected as a result of the disputed breach unless and until it has been determined in accordance with this Section 18.3 that this Agreement was materially breached, and such breach is not cured within [*] after such determination or such longer period as the arbitrator may establish.

19. **GENERAL PROVISIONS**

19.1. **Compliance.** The Parties shall conduct their business in accordance with all Applicable Laws. Without limiting the generality of the foregoing, each Party further acknowledges and ensures that it and its Affiliates, Sublicensees and subcontractors are familiar with the provisions of the United States Foreign Corrupt Practices Act, the UK Bribery Act and applicable local bribery and corruption laws, and shall not take or permit any action that will either constitute a violation under, or cause the other Party to be in violation of, the provisions of the United States Foreign Corrupt Practices Act, the UK Bribery Act or applicable local bribery and corruption law or other Applicable Laws (collectively, **"Improper Conduct").** In addition to any other rights either Party may have under this Agreement, if a Party (the **"Improper Party")** notifies the other Party of, or if such other Party otherwise has a reasonable suspicion of, the occurrence of Improper Conduct, such other Party shall have the right to have an independent auditor inspect the premises, books and records of the Improper Party relevant to such Improper Conduct for the purpose of ensuring compliance under this Section 19.1.

19.2. **Assignment and Subcontracting.** Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) LICENSOR may assign to a Third Party its rights to receive some or all of the Fees payable hereunder, (b) each Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; (c) LICENSOR may assign this Agreement in its entirety without the consent of IMMEDICA to a successor to all or substantially all of its business to which this Agreement relates; and (d) IMMEDICA may assign this Agreement in its entirety without the consent of LICENSOR to a successor to all or substantially all of its business to which this Agreement relates provided that such successor is not a Competitor. For purposes of this Section 19.2, **"Competitor"** means a Third Party that is Developing or commercializing an antibody, or another biological therapeutic molecule, directed to the Target in the Field. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b), (c) and (d) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. The LICENSOR shall not assign or otherwise transfer to any Affiliate or any Third Party any ownership interest in or to any Licensed Know-How or Licensed Patent, unless (i) the LICENSOR's entire business associated with the Product, including all Manufacturing rights relating to the Product, are assigned to such Affiliate or Third Party and (ii) this Agreement is concurrently assigned therewith. Any attempted assignment in contravention of the foregoing shall be void. Each Party shall be entitled to appoint subcontractors to carry out its obligations under this Agreement provided that such subcontractors are engaged under contracts that are consistent with the terms of this Agreement and such subcontracting shall not relieve a Party of its obligations under this Agreement.

19.3. **Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and forceable provision therefor which, as nearly possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

19.4. **Governing Law.** This Agreement and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by, and construed in accordance with, the laws of England and Wales, without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result, except that issues subject to the arbitration clause and any arbitration hereunder shall be governed by the applicable commercial arbitration rules and regulations.

19.5. **Force Majeure.** Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, pandemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a **"Force Majeure Event"),** provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. In the event that the Force Majeure Event is a recognized widespread epidemic or pandemic (including the current COVID-19 pandemic) that delays or renders impracticable or unsafe the performance by either or both of the Parties under this Agreement, the Parties will negotiate in good faith appropriate modifications to this Agreement to allow performance hereunder that is consistent with the health and safety of the Parties, their representatives, the general public and/or any participants in any Clinical Studies.

19.6. **Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

19.7. **Relationship of the Parties.** Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between LICENSOR and IMMEDICA, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

19.8. **Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

19.9. **Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt), (b) sent by email (with confirmation of receipt), provided that a copy is also sent by an internationally recognized overnight delivery service (receipt requested), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and email addresses set forth below (or to such other addresses and email addresses as a Party may designate by written notice):

If to LICENSOR:

Actinium Pharmaceuticals, Inc.
275 Madison Avenue, Suite 702
New York, New York, 10016
Email: [*]
Attention: General Counsel
With a copy addressed to the CFO at
Email: [*]

If to IMMEDICA:

Immedica Pharma AB
Norrtullsgatan 15
SE 113 29 Stockholm
Sweden
Email: [*]
Attention: General Counsel
With a copy addressed to the CEO at
Email: [*]

19.10. **Further Assurances.** IMMEDICA and LICENSOR hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

19.11. **No Third Party Beneficiary Rights.** This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

19.12. **Entire Agreement.**

(a) This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter.

(b) In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

19.13. **Interpretation.** The headings of Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word " including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement.

19.14. **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement bye- mail of a .pdf attachment shall be effective as delivery of a manually executed counterpart of this Agreement.

19.15. **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

19.16. **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

[Signature page(s) follow]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

ACTINIUM PHARMACEUTICALS, INC.

By: /s/ Sandesh Seth
Name: Sandesh Seth
Title: CEO

IMMEDICA PHARMA AB

By: /s/ Anders Edvell
Name: Anders Edvell
Title: CEO

SCHEDULE A: PATENT RIGHTS

[*]

SCHEDULE B: PAYMENTS

1. **PAYMENTS**

1.1. ***Upfront Payment. In consideration of the licenses and rights granted to IMMEDICA hereunder, IMMEDICA shall pay to LICENSOR a one-time upfront, non-refundable and non-creditable payment of US$35,000,000 (in words: thirty five million US dollars).***

1.2. **Milestone Payments.**

1.2.1. In further consideration of the licenses and rights granted to IMMEDICA hereunder, upon first achievement of each Milestone set forth below, the corresponding non-creditable and non-refundable Milestone Payments shall be payable by IMMEDICA to LICENSOR:

REGULATORY MILESTONES	**MILESTONE PAYMENT**
[*]	[*]

For the purposes of the milestones in the table above "Indication" shall mean a separate and distinct indication requiring a separate Regulatory Approval. Assuming that the first Indication is conditioning treatment for bone marrow transplantation in AML, the second and third Indications shall not be conditioning treatment for bone marrow transplant in AML.

COMMERCIAL MILESTONES	**MILESTONE PAYMENT**
[*]	[*]

1.2.2. For the avoidance of doubt: (i) each Milestone Payment shall be payable only once upon the first achievement of the applicable Milestone; (ii) satisfaction of a Milestone by an Affiliate of IMMEDICA or Sublicensee of IMMEDICA shall be deemed to have been satisfied by IMMEDICA for purposes of this Section 1.2 of Schedule B; (iii) the total Regulatory Milestones shall not, in any circumstances, exceed [*]; and (iii) the total Commercial Milestones shall not, in any circumstances, exceed [*].

1.3. **Royalties.**

1.3.1. **Royalty Rate.** In consideration of the licenses and rights granted to IMMEDICA hereunder, IMMEDICA will pay to LICENSOR Royalties on Net Sales of Product in the Territory, where such Royalties shall be calculated each Calendar Quarter by multiplying the Net Sales for such Calendar Quarter by the applicable rate set forth in the table below, subject to the provisions of this Section 1.3 of Schedule B. For clarity, the Royalties are inclusive of the cost of supply of Product under this Agreement.

TIME PERIOD OF NET SALES	**ROYALTY RATE**
[*]	[*]

1.3.2. **One Royalty:** No more than one royalty payment shall be due under this Agreement with respect to each sale of a Product in the Field in the Territory.

SCHEDULE C: THE SPECIFICATIONS

[*]

SCHEDULE D: PRESS RELEASE

[*]

Exhibit 10.2

EXECUTION COPY

AGREEMENT OF SUBLEASE

between

ABN AMRO HOLDING USA LLC

as Sublandlord

and

ACTINIUM PHARMACEUTICALS, INC.

as Subtenant

Premises: Entire 23rd Floor
100 Park Avenue
New York, New York 10017

AGREEMENT OF SUBLEASE

THIS AGREEMENT OF SUBLEASE (this "Sublease"), made and entered into as of the __ day of April, 2022, by and between ABN AMRO HOLDING USA LLC, a Delaware limited liability company, having offices at 100 Park Avenue, New York, New York 10017 ("Sublandlord"), and ACTINIUM PHARMACEUTICALS, INC., a Delaware corporation, having offices at 275 Madison Avenue, New York, New York 10016 ("Subtenant").

W I T N E S S E T H:

WHEREAS, SLG 100 Park LLC, ("Landlord") leased to Sublandlord's predecessor-in interest certain premises (the "Original Premises") at 100 Park Avenue, New York, New York 10017 (the "Building"), pursuant to a certain Lease Agreement (the "Original Lease") dated as of July 10, 2009, as amended by a certain First Lease Modification and Additional Space Agreement (the "First Amendment") dated as of March 1, 2011, a certain Second Lease Modification and Additional Space Agreement (the "Second Amendment") dated as of January 31, 2014 and a certain Third Lease Modification and Additional Space Agreement (the "Third Amendment") dated as of March 31, 2017, (the Original Lease, as amended by the First Amendment, the Second Amendment and the Third Amendment, is hereinafter referred to as the "Lease" and the premises currently leased by Sublandlord pursuant to the Lease are hereinafter referred to as the "Premises"); and

WHEREAS, Subtenant desires to sublease the entire 23rd floor portion of the Premises (the "Subleased Premises") consisting of approximately 10,889 rentable square feet, as more particularly described in "Exhibit A" which is attached to this Sublease as an integral part hereof, from Sublandlord, and Sublandlord is willing to sublease the Subleased Premises to Subtenant, upon the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and obligations herein contained, the parties hereby agree as follows:

1. Subleased Premises. Sublandlord hereby subleases the Subleased Premises to Subtenant, and Subtenant hereby hires the Subleased Premises from Sublandlord, upon and subject to the terms and conditions set forth herein.

2. Term of Sublease. The term of this Sublease (the "Term") shall commence on the later of (a) the date upon which a written consent to this Sublease is issued by Landlord following the signing of this Sublease by Sublandlord and Subtenant and (b) June 1, 2022 (the "Commencement Date"), and shall terminate on July 30, 2027 (the "Expiration Date"), unless sooner terminated as provided herein. Sublandlord shall deliver vacant possession of the Subleased Premises to Subtenant in their "as is" condition and broom clean on the Commencement Date, and Subtenant shall accept such possession.

3. Fixed Rent.

(a) Subject to the increases stipulated in Paragraph 4(b) below, during the term of this Sublease, Subtenant shall pay Sublandlord fixed rent ("Fixed Rent") for the Subleased Premises in the amount of Five Hundred Ninety Eight Thousand Eight Hundred Ninety Five and 00/100 Dollars ($598,895.00) per annum, payable in advance in equal monthly installments of Forty Nine Thousand Nine Hundred Seven and 92/100 Dollars ($49,907.92) on or before the first day of each month.

(b) Notwithstanding anything to the contrary in the foregoing, Subtenant shall pay the first monthly installment of Fixed Rent upon the signing of this Sublease by Subtenant.

(c) The Fixed Rent for any portion of a calendar month falling within the Term shall be prorated.

(d) Fixed Rent and all other amounts payable by Subtenant to Sublandlord under this Sublease (such other amounts are herein called "Additional Rent") shall be paid promptly when due, without notice or demand therefor, without deduction, abatement, counterclaim, or setoff of any kind for any reason whatsoever.

(e) Fixed Rent and Additional Rent shall be paid in U.S. Dollars and by wire transfer or ACH to such account of Sublandlord as Sublandlord may from time to time designate by notice to Subtenant.

(f) Notwithstanding the foregoing, provided that Subtenant is not then in default under this Sublease, the Fixed Rent payable for the first five (5) months after the Commencement Date shall be abated at no cost or expense to Subtenant. If Subtenant during such five (5) month abatement period defaults (after a failure to cure following any applicable notice and cure period) under this Sublease, the rent abatement for the balance of such period shall be forfeited, and Subtenant shall pay to Sublandlord, within five (5) days after demand, the Fixed Rent which would have been payable for the prior portion of the abatement period but for the abatement.

4. Additional Rent.

(a) Except as otherwise provided herein, during the term of this Sublease, Subtenant shall pay Sublandlord as Additional Rent all amounts payable by Sublandlord to Landlord as Additional Rent for the Subleased Premises pursuant to the Lease as and when such amounts are due under the Lease.

(b) In lieu of payments on account of "Expenses" and "Real Estate Taxes" (as those terms are defined in the Lease), the parties agree that the Fixed Rent payable by Subtenant pursuant to Paragraph 3(a) above shall be increased annually at a compound rate of two percent (2%) per annum, with the increases to take place on the first anniversary of the Commencement Date and on each subsequent anniversary thereof.

(c) During the term of this Sublease, Subtenant shall pay Sublandlord for electricity supplied to the Subleased Premises at the rate of 105% of Landlord's Cost (as defined in the Lease) of the Subtenant's usage as shown on the submeter located in Subleased Premises as and when payments on account of electricity are due under the Lease.

(d) In the case of any of Additional Rent payments which are not due on a regular basis on the first day of the month, Sublandlord shall give Subtenant fifteen (15) days' prior written notice thereof.

5. Subordination to and Incorporation of Lease, Etc.

(a) Obligations. Subtenant confirms that it has read the Lease and is familiar with all of the terms and provisions set forth therein. Subject to the modifications and exclusions set forth in this Sublease, the terms, provisions , covenants, stipulations, conditions, rights, obligations, remedies, agreements and definitions contained in the Lease are incorporated herein by reference and are made a part hereof and shall, as between Sublandlord and Subtenant (as if they were the "Landlord" and the "Tenant," respectively, under the Lease and as if the Subleased Premises were the Premises referred to in the Lease), constitute the terms of this Sublease as if herein set forth at length, mutatis mutandis, except to the extent that they do not relate to the Subleased Premises or are inapplicable, inconsistent with, or modified by the terms of this Sublease, and except as otherwise set forth herein. Subtenant agrees to observe, carry out, perform and discharge the terms and provisions of the Lease as they relate to the Subleased Premises to the extent required to be observed, carried out, performed or discharged by Sublandlord thereunder, except where inapplicable or inconsistent with the terms of this Sublease.

(b) Subordination, Etc. Subtenant hereby agrees that (i) this Sublease is and shall remain in all respects subject and subordinate to the Lease and to any matters to which the Lease is or shall be subordinate, (ii) except to the extent otherwise expressly permitted by this Sublease, Subtenant will occupy the Subleased Premises in accordance with the terms of the Lease, will maintain the Subleased Premises in accordance with the provisions of the Lease as though it were the "Tenant" thereunder and will not do or cause to be done, or suffer any act or omit to do, any act which might result in a violation of or a default under any of the terms, conditions, covenants or agreements of the Lease.

(c) Conflicting Terms. Except as otherwise specifically provided herein, in the event that any term and/or condition of this Sublease shall conflict with, or be inconsistent with, any term and/or condition of the Lease, this Sublease will govern, unless such term and/or condition would constitute a default under or breach of the Lease, in which case the Lease will govern. Subtenant shall not take or suffer any action which would constitute a default under, or be a violation of, the Lease.

(d) Excluded Articles. The following provisions of the Lease shall be deemed to be excluded from this Sublease: (i) Original Lease – Section 1.01; Article 2; Article 3; Article 5; Article 12; Sections 13.01 through 13.03 and Section 3.05 (as they provide for Nondisturbance Agreements); Section 13.11; Section 13.12; Article 17; Article 18; Article 22; Section 25.01 (second sentence); Article 27; Article 29; Article 31; Article 40; Article 48; Article 50; Article 51; Article 52; Exhibit A; Exhibit B; Exhibits F-1 and F-2; Exhibit I; Exhibit J and Exhibit K; (ii) First Amendment – Sections 3.2 through 3.6; Articles 4 through 6; Section 7.1 (last sentence); Articles 8 through 12; and Exhibits B through D; (iii) Second Amendment – Articles 3 through 13; and Exhibits A through D; and (iv) Third Amendment –Articles 3 through 13; Exhibits A through Exhibit C.

(e) Termination of Lease. In the event that the term of the Lease is terminated prior to the Expiration Date, this Sublease shall automatically cease and terminate on the date of such termination. In the event of such termination, Sublandlord shall return to Subtenant that portion of Fixed Rent and Additional Rent paid in advance by Subtenant, if any, pro-rated as of the date of such termination. Sublandlord agrees that, without the prior written consent of Subtenant, it will not voluntarily agree with Landlord to terminate the Lease with respect to the Subleased Premises prior to the Expiration Date.

(f) Entry and Inspection. Sublandlord shall have the right to enter and inspect the Subleased Premises pursuant to the applicable provisions of the Lease during business hours (except in an emergency) and upon notice (which may be given orally). Sublandlord agrees that Subtenant and its agents may have access to the Subleased Premises prior to the Commencement Date, provided that it gives Sublandlord notice of each proposed access at least twenty-four (24) hours in advance. Such access shall be only for taking measurements and other planning purposes.

(g) Services. Subtenant shall be entitled to the services, utilities and repairs which Landlord is obligated to furnish or make to Sublandlord with respect to the Subleased Premises pursuant to the terms of the Lease, but Sublandlord shall have no obligation to make any repairs or provide such utilities or services. Sublandlord shall in no event be liable to Subtenant nor shall the obligations of Subtenant thereunder be impaired, or the performance thereof be excused, because of any failure or delay on the part of Landlord in furnishing such services or in making such repairs unless such failure or delay results from a default by Sublandlord under the Lease. If Landlord shall default in any of its obligations to perform services with respect to the Subleased Premises, Sublandlord, at the reasonable cost of Subtenant, will reasonably assist Subtenant's efforts to obtain such services from Landlord.

(h) Consents and Notices. In all provisions of this Sublease (including provisions of the Lease incorporated hereby) requiring the approval or consent of Sublandlord, Subtenant shall be required to obtain the approval or consent of Sublandlord as well as the approval or consent of Landlord. At the request of Subtenant, Sublandlord shall promptly apply to Landlord for any such approval or consent. In all provisions of this Sublease (including provisions of the Lease incorporated hereby) requiring that notice be given, Subtenant shall be required to give notice to both Sublandlord and Landlord. Notwithstanding anything to the contrary set forth in this Sublease, any covenants, representations or other undertakings of Landlord under the Lease shall not be deemed to be made by, or otherwise constitute obligations of, Sublandlord under this Sublease.

(i) Landlord's Consent to Sublease.

(A) Sublandlord shall, promptly after execution of this Sublease by both parties, submit a copy of same to Landlord and shall use all reasonable efforts to obtain Landlord's consent to this Sublease; provided, however, that Sublandlord shall not be required to make any payment or commence any action or proceeding in order to obtain Landlord's consent to this Sublease and shall not in any event be liable to Subtenant for any failure to obtain same (as long as Sublandlord shall have used all reasonable efforts as aforesaid to obtain Landlord's consent to this Sublease). Subtenant shall fully cooperate with Sublandlord in order to obtain Landlord's consent to this Sublease, including, but not limited to, promptly supplying such financial, business or other information or documentation as Landlord may reasonably request of Sublandlord in connection with this Sublease. In the event that Landlord's consent to this Sublease is not obtained within thirty five (35) days after the date of this Sublease, either party may terminate this Sublease at any time prior to the issuance of such consent by giving written notice of termination to the other party. If this Sublease is terminated pursuant to the immediately preceding sentence of this Paragraph 5(i)(A), Sublandlord shall promptly return to Subtenant the first monthly installment of Fixed Rent which was paid by Subtenant pursuant to Paragraph 3(b) above and the Security Deposit which was submitted by Subtenant pursuant to Paragraph 19(a) below and, except as aforesaid, neither party shall have any further obligation to the other party under this Sublease.

(B) Landlord's consent to this Sublease shall not be deemed or construed to modify, amend or affect the terms and provisions of the Lease, or Sublandlord's obligations thereunder, which shall continue to apply to the Premises, including the Subleased Premises, and the occupants thereof, as if the Sublease had not been made.

6. Use of Subleased Premises: Quiet Enjoyment.

(a) Subtenant covenants that it will use and occupy the Subleased Premises solely for the purposes expressly permitted by the Lease.

(b) As long as Subtenant pays, when due, all Fixed Rent and Additional Rent due hereunder and performs and observes all of the terms, covenants and conditions of this Sublease and the Lease, Subtenant shall have, hold and enjoy the Subleased Premises peaceably and quietly during the Term hereof without hindrance or molestation by Sublandlord, or any party claiming through or under Sublandlord, subject to the terms and conditions of this Sublease and the Lease.

7. Improvements. Subtenant shall be entitled to make alterations, improvements and other changes (collectively hereinafter referred to as "Sublease Improvements") to the Subleased Premises in accordance with the applicable provisions of the Lease and this Sublease, including the installation of supplemental air conditioning units and/or handling equipment (it being understood that Sublandlord makes no representation as to the availability of condenser water for any such supplemental units for purchase from Landlord). All such Sublease Improvements shall be subject to the prior written consent of Sublandlord and Landlord. All Sublease Improvements shall be performed by Subtenant at its sole cost and expense. Subtenant's rights and obligations with respect to Sublease Improvements shall be governed and limited by the relevant provisions of the Lease and this Sublease. Subtenant shall reimburse Sublandlord, within ten (10) days after written demand, for all reasonable actual out-of-pocket costs incurred by Sublandlord for reviewing Subtenant's plans for any proposed Sublease Improvement and for assisting Subtenant to obtain Landlord's consent thereto.

8. Default by Subtenant.

(a) The following shall constitute events of default (each an "Event of Default"):

(i) if (A) Subtenant shall fail to pay any Fixed Rent or Additional Rent on the due date thereof and such default shall continue for a period of seven (7) days after notice by Sublandlord to Subtenant of such default (provided, however, that Sublandlord shall not be required to deliver such notice more than two (2) times in any twelve (12) month period, it being understood that any further failure to pay any Fixed Rent or Additional Rent on the due date thereof within such twelve (12) month period shall constitute an immediate Event of Default), or (B) Subtenant shall fail to comply with any term, provision or covenant of this Sublease or any applicable term, provision or covenant of the Lease, or Subtenant shall violate any rules and regulations now or hereafter established for the operation of the Building and Subtenant shall fail to remedy such failure within fifteen (15) days after written notice from Sublandlord, or if such failure complained of shall be of a nature that the same cannot be completely cured and remedied within said fifteen (15) day period, and Subtenant shall not (1) promptly upon the giving by Sublandlord of such notice, advise Sublandlord of Subtenant's intention to institute all steps necessary to remedy such situation, (2) promptly institute and thereafter diligently pursue all steps necessary to remedy the same and (3) effect such remedy within a reasonable time (not to exceed sixty (60) days) after the date of the giving of said notice by Sublandlord and in any event prior to such time as would either (y) subject Landlord, Sublandlord, Sublandlord's agents or any mortgagee or ground lessee to civil or criminal liability or prosecution for a crime, or (z) cause a default under any applicable mortgage or ground lease; or

(ii) if (A) any petition is filed by Subtenant under any provision of Federal or state bankruptcy laws or other statute whether domestic or foreign involving creditors' rights or the insolvency of debtors or any such petition is filed against Subtenant and Subtenant fails to secure a dismissal or stay thereof within thirty (30) days, or (B) Subtenant shall become insolvent or make an assignment for the benefit of creditors, or (C) a receiver is appointed for all or substantially all of the assets of Subtenant and Subtenant fails to secure a dismissal or stay thereof within sixty (60) days, or (D) all or a material portion of the Subleased Premises shall be abandoned, deserted or vacated.

(b) Upon the occurrence of an Event of Default, Sublandlord shall have the right, at its option, to do and perform any one or more of the following, in addition to, and not in limitation of any other remedy or right permitted it by law, by this Sublease or by the Lease:

(i) terminate this Sublease, in which event Subtenant shall immediately surrender the Subleased Premises to Sublandlord, but if Subtenant shall fail to do so, Sublandlord may, without prejudice to any other right or remedy Sublandlord may have, either by law or under this Sublease or otherwise, obtain possession or rent in arrears or damages for breach of contract, enter upon the Subleased Premises and expel or remove Subtenant and Subtenant's personal property, with or without force and without being liable to Subtenant, and Subtenant agrees to indemnify and hold Sublandlord harmless for all losses or damage which Sublandlord may suffer by reason of such termination, whether through inability to relet the Subleased Premises or through decrease in rent or by damage to the Subleased Premises, or otherwise, or

(ii) enter the Subleased Premises and remove Subtenant and its personal property therefrom without terminating this Sublease or being liable to Subtenant in any manner whatsoever for such acts, and, at Sublandlord's option, relet the Subleased Premises as the agent of Subtenant and receive rent therefor, and in such event Subtenant shall be liable on a monthly basis when rent is otherwise due and payable to Sublandlord for any deficiency which may arise by reason of such reletting during the remainder of the Term of this Sublease, but shall not be entitled to any surplus so arising. In the event of a conflict between the provisions of this Paragraph 8 and the provisions of the Lease, the provisions of this Paragraph 8 shall prevail.

9. Subletting and Assignment.

(a) Subtenant shall not assign, mortgage, pledge, encumber or in any manner transfer this Sublease or any part thereof nor sublet or suffer the Subleased Premises or any part thereof to be used by others, except as expressly permitted by this Sublease and the Lease. It is understood that a change in control of Subtenant shall be deemed to constitute an assignment of this Sublease. The provisions of the Lease relating to assignment and subletting shall be deemed to be incorporated into this Sublease.

(b) If this Sublease is assigned in violation of the provisions of this Sublease, Sublandlord may and is hereby empowered to collect rent from the assignee. In such event, Sublandlord may apply the net amount received by it to the Fixed Rent, Additional Rent or any other payments herein reserved or provided for, and no such collection shall be deemed a waiver of the covenant herein against assignment, mortgage, pledge or encumbrance, or an acceptance of the assignee as a tenant or subtenant under this Sublease or a release of Subtenant from the further performance of its covenants herein. If the Subleased Premises or any part thereof is sublet or occupied by others in violation of the provisions of this Sublease, Sublandlord is hereby empowered to collect rent from the subtenant or other occupant, and to apply the same to the curing of any default hereunder in any order of priority Sublandlord may elect, any unexpended balance to be applied by Sublandlord against any rental or other obligations subsequently becoming due. The making of any assignment, mortgage, pledge, encumbrance or subletting in whole or in part, and whether or not in violation of the provisions of this Sublease, shall not operate to relieve Subtenant from its obligations under this Sublease and, notwithstanding any such assignment, mortgage, pledge, encumbrance or subletting, Subtenant shall remain liable for the payment of all Fixed Rent, Additional Rent and other charges and for the due performance of all the covenants, agreements, terms and provisions of this Sublease until the end of the Term. Each and every assignee, whether as assignee or as successor in interest of Subtenant or as assignee or successor in interest of any assignee, shall immediately be and become and remain liable jointly and severally with Subtenant and with each other for the payment of the Fixed Rent, Additional Rent and other charges payable under this Sublease and for the due performance of all the covenants, agreements terms and provisions of this Sublease on the part of Subtenant to be paid and performed until the end of the Term.

(c) Any proposal by Subtenant to assign this Sublease or to further sublet the Subleased Premises or any portion thereof shall be subject to the prior written consent of Landlord and Sublandlord. Sublandlord's consent to a proposed assignment or subletting of the Subleased Premises shall be deemed to have been granted provided that Landlord has given its consent therefor. Subtenant shall reimburse Sublandlord for all reasonable out-of-pocket expenses incurred in connection with a proposed assignment or subletting.

10. Liability Insurance.

(a) Neither Sublandlord nor its successors, assigns, employees or agents shall be liable for any loss of or damage to property of Subtenant or Subtenant's subtenants, assigns, employees, agents or visitors, except for loss or damage resulting from Sublandlord's gross negligence or willful misconduct. With respect to the Subleased Premises, Sublandlord, its successors, assigns, employees and agents shall not be liable for any injury or damage to persons or property except for loss or damage resulting from the gross negligence or willful misconduct of Sublandlord, its successors, assigns, employees and agents.

(b) Subtenant shall maintain with respect to the Subleased Premises comprehensive general public liability insurance, property insurance and other insurance in the manner and with the minimum limits set forth in the Lease, with insurance companies qualified to do business in the State of New York and otherwise meeting the standards set forth in the Lease, insuring Subtenant, Sublandlord, Landlord and any other parties required in accordance with the Lease as named insureds, against, inter alia, claims and liabilities for bodily injury or death to persons, and damage to property. Each party shall look exclusively to any insurance carried by it pursuant to this Sublease and the Lease for loss or damage to property resulting from the negligence of the other party or its agents, servants, employees, contractors, invitees or licensees, and, to the extent permitted by law, Sublandlord and Subtenant each hereby releases and waives all right of recovery against the other or anyone claiming through or under each of them by way of subrogation or otherwise, provided that such waivers of liability are permitted and are available under both Sublandlord's and Subtenant's policies of insurance or such waivers are approved by their insurance carriers. Each party agrees to pay the added cost, if any, of obtaining such approval from its insurance carrier. Subtenant shall deliver certificates of insurance to Sublandlord with respect to all insurance required under this Sublease and the Lease on or before the signing of this Sublease by Subtenant. Each of Subtenant's policies of insurance shall provide that such policy may not be materially changed, amended, canceled or allowed to lapse except upon thirty (30) days' prior notice to Sublandlord, Landlord and any other parties required in accordance with the Lease. Such insurance shall be subject to Sublandlord's approval as to form, content, coverage and expiration dates, which approval shall be deemed granted if not refused within fifteen (15) days after delivery of the certificates of insurance to Sublandlord.

11. Indemnification. Except as provided in Paragraph 10 hereof, Subtenant shall indemnify and hold harmless Sublandlord from and against all claims, losses, costs, damages, expenses and liabilities (including, but not limited to, the costs of legal proceedings and reasonable attorneys' fees and disbursements) which Sublandlord may incur, pay or have asserted against it by reason of any injuries to persons occurring in, on or about the Subleased Premises caused by the acts or omissions of Subtenant, its agents, employees, guests or invitees or by reason of any breach, failure or default hereunder on Subtenant's part, including any breach or default which results in a breach of or possible termination or forfeiture of the Lease. In the event of a conflict between the provisions of this Paragraph 11 and any provision of the Lease, the provisions of this Paragraph 11 shall prevail. The provisions of this Paragraph 11 shall survive the expiration or earlier termination of this Sublease.

12. Subtenant's Rights. Notwithstanding anything to the contrary herein set forth, Subtenant shall in no case have any rights in respect of the Subleased Premises greater than the rights of Sublandlord under the Lease.

13. Possession, Care and Condition of Subleased Premises.

(a) Possession and Condition. Subtenant acknowledges that it has examined the Subleased Premises and that it is leasing the Subleased Premises in their "as is" condition. Sublandlord shall have no obligation to perform any work or supply any materials to prepare the Subleased Premises for Subtenant's occupancy. Subject to Paragraph 7 above, Subtenant shall, at its sole cost and expense, make any alterations and improvements that it requires to prepare the Subleased Premises for its occupancy thereof. Sublandlord has made no representation or warranty concerning the condition of the Subleased Premises except as expressly set forth in this Sublease. Notwithstanding the forgoing, Sublandlord shall grant to Subtenant a work allowance in the amount of One Hundred Thousand and 00/100 Dollars ($100,000.00) (the "Allowance") to be utilized by Subtenant for the hard and soft costs of the work to be done by Subtenant to prepare the Subleased Premises for its occupancy ("Subtenant's Work"). Subtenant's Work shall be deemed to be Subtenant Improvements for purposes of this Sublease, and the terms and provisions of Paragraph 7 above shall be applicable thereto. Upon completion of Subtenant's Work, Subtenant's shall submit to Sublandlord: (a) copies of bills and receipts indicating that all contractors, sub-contractors and soft cost providers performing or supporting the performance of Subtenant's Work have been paid in full, (b) the documents identified in Section 8.1 (a)(iii), items (iii), (iv) and (v) of the First Amendment and (c) the document identified in Section 8.1 (d), item (x) of the First Amendment. Within twenty (20) days after submission of the foregoing items and a requisition showing the total amount expended on Subtenant's Work, and provided that Subtenant is not then in default under this Sublease, Sublandlord shall pay to Subtenant the lesser of the amount indicated in Subtenant's requisition and the amount of the Allowance.

(b) Included Property. Sublandlord shall leave the furniture, fixtures and equipment which are presently situated in the Subleased Premises, and which are identified in Exhibit "B" which is attached hereto as an integral part hereof (the "Included Property") in the Subleased Premises. Subtenant shall take possession of the Included Property in its "as is", "where is" condition. Sublandlord makes no representations or warranties with respect to the Included Property. The Included Property shall remain the property of Sublandlord, and Subtenant shall exercise the care of a prudent custodian in its use and care of the Included Property during the Term. Notwithstanding the foregoing, if this Sublease has not then been terminated in accordance with the terms hereof, then, on July 1, 2027 title to the Included Property shall, without any action on the part of the Sublandlord or Subtenant, be transferred to Subtenant and Subtenant shall thereupon be the owner of the Included Property for all purposes. Thereafter, upon the expiration of the Term, Subtenant at its sole cost and expense, shall remove the Included Property from the Subleased Premises. If Subtenant shall fail to remove any of the Included Property, Sublandlord may arrange for such removal and the costs of such removal plus an incremental amount of fifteen percent (15%) shall be paid to Sublandlord by Subtenant within fifteen (15) days after demand therefor. In addition to the Included Property, Sublandlord shall leave the existing supplemental air conditioning unit (the "A/C Unit") which services the IDF closet in the Subleased Premises for Subtenant's use. Sublandlord makes no representation as to the condition of the Unit. It shall be the responsibility of Subtenant to maintain the Unit, to carry a maintenance contract covering the Unit and to replace the Unit, if necessary.

(c) Restoration of Subleased Premises. On the date upon which the term hereof shall expire and come to an end, whether by expiration, by lapse of time or otherwise, Subtenant, at its sole cost and expense, shall quit and surrender the Subleased Premises to Sublandlord in good order and condition and broom clean. Prior to such date, Subtenant, at its sole cost, shall remove all of the Sublease Improvements it (or such portion thereof as shall be required by Landlord) and otherwise restore the Subleased Premises to its condition on the Commencement Date.

(d) Freight Elevator. Sublandlord shall pay for or reimburse Subtenant for up to ten (10) hours of overtime freight elevator usage for Subtenant's move-in to the Subleased Premises.

(e) Holdover. Notwithstanding anything to the contrary provided elsewhere in this Sublease, if Subtenant holds over in the Subleased Premises after the Expiration Date, Subtenant shall pay to Sublandlord within five (5) days after demand in each case one hundred twenty five percent (125%) of all amounts that Sublandlord is required to pay Landlord on account of such holdover. In addition, Subtenant shall be liable to Sublandlord for all damages (including consequential damages), costs and expenses (including attorneys' fees and expenses) incurred by Sublandlord as a consequence of the holdover.

(f) Obligation to Repair. Subtenant shall take good care of the Subleased Premises and the fixtures and appurtenances therein. All damage or injury to the Subleased Premises and to its fixtures, appurtenances and equipment or to the Building caused by Subtenant's moving of Subtenant's property in or out of the Building or by Subtenant's installation or removal of furniture, fixtures or other property, or resulting from Subtenant's negligent acts, omissions or misconduct shall be promptly repaired by Subtenant, at its sole cost and expense, to the reasonable satisfaction of Sublandlord and Landlord. If a request is made by Landlord for Sublandlord to make reasonable repairs the Subleased Premises in accordance with the Lease, Subtenant shall undertake such repair at its cost in accordance with the Lease. All of said repairs required to be made by Subtenant shall be in quality and class equal to the original work or installation and shall be done in a good and workmanlike manner. If Subtenant fails to make such repairs, the same may be made by Sublandlord or Landlord at the expense of Subtenant and all sums so spent and expenses incurred by Sublandlord plus an incremental amount of fifteen percent (15%) of such sums shall be collectible as Additional Rent and shall be paid by Subtenant to Sublandlord within five (5) days after rendition of a bill or statement therefor.

14. Notices. Notices, demands and any other communications hereunder shall be in writing and shall be given or made by personal delivery, by overnight delivery by a recognized national courier service or by certified mail, return receipt requested, addressed to the parties at the addresses hereinabove set forth (and, in the case of Sublandlord, addressed to the attention of its Chief Operating Officer with a copy addressed to the attention of its General Counsel), or such other address which either party may hereafter designate for such purpose by a written notice. Notices, demands and other communications shall be deemed given (a) if delivered by personal delivery or by overnight courier service, on the date of delivery or rejection of delivery, or (b) if sent by certified mail, upon receipt or rejection of such delivery. Sublandlord shall, within five (5) days after receipt thereof, give to Subtenant a copy of each notice or demand received from Landlord relating to the Subleased Premises, and Subtenant shall, within five (5) days after receipt thereof, give to Sublandlord a copy of each notice or demand received from Landlord relating to the Subleased Premises.

15. Miscellaneous. This Sublease contains the entire agreement of the parties with respect to the transactions contemplated hereby, supersedes all prior agreements or understandings between the parties (except as otherwise provided herein) and may not be changed or modified in any way unless such change or modification is in writing and signed by the parties hereto. Neither Sublandlord nor Subtenant has made any representations or warranties with respect to this Sublease except as set forth herein. If any provision of this Sublease shall be held to be invalid or unenforceable in any respect, the validity or enforceability of the remaining portions of this Sublease shall be unaffected thereby. This Sublease shall be binding upon, inure to the benefit of and be enforceable by the parties hereto and their respective successors and assigns. The headings in this Sublease are for convenience only and shall not be used in construing the intentions of the parties. This Sublease shall be governed by and construed in accordance with the laws of the State of New York. Sublandlord and Subtenant each represents that it has full right and authority to enter into this Sublease and that the officer signing this Sublease on its behalf is authorized to do so. This Sublease may be signed in counterparts, each of which shall constitute an original but all of which, when taken together, shall constitute one instrument. Faxed signatures, emailed copies of signatures and signatures exchanged via PDF or other electronic means shall be binding to the same extent as original signatures. Sublandlord and Subtenant each waives, to the extent permitted by law, the right to a jury trial in any action or legal proceeding between the parties arising out of this Sublease or Subtenant's occupancy of the Subleased Premises.

16. Attorneys' Fees. If either party hereto is made or becomes a party to any litigation commenced by or against the other party involving the enforcement of any of the rights and remedies of such party, or arising on account of the default of the other party in the performance of such party's obligations hereunder, then the prevailing party in such litigation, or the party becoming involved in such litigation because of a claim against such other party, as the case may be, shall be reimbursed by the other party for all costs and reasonable attorneys' fees incurred by such party in such litigation.

17. Interest; Late Charges. Subtenant shall, on demand, pay interest on any Fixed Rent, Additional Rent and other amounts payable by Subtenant to Sublandlord pursuant hereto if any such amount is received after its due date. Interest for each calendar month or portion thereof shall be at the rate of one and one-half percent (1½%) of the overdue amount (but in no event in excess of the maximum rate permitted by law). In addition, if any Fixed Rent, Additional Rent or other amount payable by Subtenant to Sublandlord pursuant hereto is not paid within ten (10) days after its due date, Subtenant shall pay to Sublandlord a late charge of five cents ($.05) for each Dollar of the overdue amount to defray Sublandlord's administrative costs for handling the late payment. The right of Sublandlord to collect interest and late charges shall be without derogation of any other right of Sublandlord hereunder, the amounts payable under this Paragraph 17 shall be deemed to be Additional Rent for purposes of this Sublease.

18. Brokerage. Sublandlord and Subtenant each represents and warrants to the other that it has had no dealings or communications with any broker or agent in connection with this Sublease other than Jones Lang LaSalle Brokerage, Inc. and Lee & Associates (the "Brokers"). In the event any broker or agent other than the Brokers claims that it is entitled to a commission due to the acts of Sublandlord or Subtenant, such party covenants and agrees to pay, hold harmless and indemnify the other party from and against any and all costs, expenses or liability incurred by the other party in connection with or relating to any claims for compensation, commissions and fees asserted by such broker or agent with respect to this Sublease or the negotiation hereof (including, without limitation, the cost of legal fees and related expenses incurred in connection with defending against such claims). Sublandlord agrees to pay the commissions owing to the Brokers pursuant to a separate agreement or agreements.

19. Security.

(a) As security for the full and punctual performance by Subtenant of all of the terms and conditions of this Sublease, Subtenant shall submit to Sublandlord on or before the date that it signs this Sublease and shall maintain throughout the term of this Sublease a security deposit in the amount of Two Hundred Ninety Nine Thousand Four Hundred Forty Seven and 50/100 Dollars ($299,447.50) (the "Security Deposit"). The Security Deposit shall take the form of an irrevocable standby letter of credit in form and substance satisfactory to Sublandlord (the "Letter of Credit") issued by a commercial bank which is a member of the New York Clearing House Association or another commercial bank which is acceptable to Sublandlord and shall have an initial term which is not less than one (1) year from its date of issuance. The Letter of Credit shall provide that Sublandlord may draw thereunder by the submission of only a sight draft and, unless otherwise agreed by Sublandlord, shall permit Sublandlord to make presentment thereunder at an office of the bank located in the City of New York. In each case, the Letter of Credit shall further provide that Sublandlord may draw the full amount thereof if it is not extended for an additional one (1) year period at least forty five (45) days prior to its stated expiration date. The final Letter of Credit issued hereunder shall have an expiration date which is no early than ninety (90) days after the Expiration Date. Each Letter of Credit shall be in form and substance fully satisfactory to Sublandlord.

(b) Whenever Subtenant is in default under this Sublease and such default has continued after any applicable written notice has been delivered to Subtenant and beyond any applicable cure period or whenever Sublandlord has obtained a judgment against Subtenant based on a claim arising out of this Sublease, Sublandlord may draw the amount of such default or judgment, as the case may be, from the Security Deposit, to the extent required for the payment of any Fixed Rent or Additional Rent or for any sum which Sublandlord may expend or be required to expend by reason of Subtenant's default.

(c) In the case of every use, application or retention of the Security Deposit, Subtenant shall, within three (3) days after demand, replenish the Security Deposit to the amount which Subtenant is required to maintain hereunder and the failure to do so shall constitute an Event of Default hereunder without any notice or cure period.

(d) In lieu of the Letter of Credit, Subtenant shall have the option of submitting the Security Deposit in cash on or before the date that it signs this Sublease; provided, however, that, in such case, Subtenant shall substitute a Letter of Credit which meets the requirements of Paragraph 19(a) above for the cash Security Deposit within sixty (60) days after the date of this Sublease and the failure of Subtenant to do so shall constitute an Event of Default hereunder without any notice or cure period. Sublandlord shall return the cash Security Deposit to Subtenant immediately after its receipt of the Letter of Credit.

20. Consent to Jurisdiction. Each of the parties hereto hereby irrevocably consents and agrees that any legal action or proceeding with respect to this Sublease may be brought in any of the Federal or state courts having subject matter jurisdiction located in the Borough of Manhattan, The City of New York, and, by its execution and delivery of this Sublease, each such party hereby (a) accepts the non-exclusive jurisdiction of the aforesaid courts, (b) irrevocably agrees to be bound by any final judgment (after any appeal) of any such court with respect to this Sublease, and (c) irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of venue of any suit, action or proceeding with respect to this Sublease brought in any such court, and further irrevocably waives, to the fullest extent permitted by law, any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

21. Representations and Warranties. Sublandlord hereby represents and warrants to Subtenant that, as of this date, Sublandlord has not received from Landlord or given to Landlord any notice of a default under the Lease and, to the best of its knowledge, no default under the Lease currently exists. Further, Sublandlord represents and warrants to Subtenant that, as of this date, the Lease is in full force and effect.

IN WITNESS WHEREOF, this Sublease has been executed by the duly authorized representatives of the parties as of the day and year first above written.

SUBLANDLORD:

ABN AMRO HOLDING USA LLC

By: _____
Name:
Title:

SUBTENANT:

ACTINIUM PHARMACEUTICALS, INC.

By: _____
Name:
Title:

SUBTENANT ACKNOWLEDGEMENT

STATE OF NEW YORK)
) ss.:
COUNTY OF-NEW YORK)

On the __ day of _____, 2022, before me, the undersigned, a Notary Public in and for said state, personally appeared _____ who proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that he (she) executed the same in his (her) capacity , and that by his (her) signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument.

Notary Public

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Sandesh Seth, certify that:

1. I have reviewed this Form 10-Q of Actinium Pharmaceuticals, 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. I am 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 13-a-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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. 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.

Dated: August 12, 2022

By: /s/ Sandesh Seth
Sandesh Seth
Chairman and Chief Executive Officer
(Duly Authorized Officer,
Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Steve O'Loughlin, certify that:

1. I have reviewed this Form 10-Q of Actinium Pharmaceuticals, 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. I am 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 13-a-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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. 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.

Dated: August 12, 2022

By: /s/ Steve O'Loughlin
Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer,
Principal Financial and Accounting 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

In connection with the Quarterly Report of Actinium Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sandesh Seth, Chairman & CEO of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: August 12, 2022

By: /s/ Sandesh Seth
Sandesh Seth
Chairman and Chief Executive Officer
(Duly Authorized Officer,
Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Actinium Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steve O'Loughlin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: August 12, 2022

By: /s/ Steve O'Loughlin
Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer,
Principal Financial and Accounting Officer)