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DELTA REPORT

10-Q

AIM - AIM IMMUNOTECH INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1235
CHANGES	6
DELETIONS	1227
ADDITIONS	2

REFINITIV

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

FORM 10-Q

☒ Quarterly Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
For the Quarterly Period Ended September 30, 2023
Commission File Number: 001-27072

AIM IMMUNOTECH INC.

(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2117 SW Highway 484, OcalaFL34473
(Address of principal executive offices) (Zip Code)
(352)448-7797
(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 each exchange on which registered
Common Stock, par value $0.001 per share	AIM	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 such shorter period that the registrant was required to submit and post such files).
☒Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definition 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 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
48,841,656 shares of common stock were outstanding, and 689 shares of series B preferred stock were outstanding as of November 12, 2023.

PART I- FINANCIAL INFORMATION

ITEM 1: Financial Statements

AIM IMMUNOTECH INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except for share and per share amounts)

(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,264	$ 27,053
Marketable investments	7,167	7,137
Funds receivable from New Jersey net operating loss	48	1,676
Prepaid expenses and other current assets	263	455
Total current assets	22,742	36,321
Property and equipment, net	136	195
Right of use asset, net	727	829
Patent and trademark rights, net	2,154	1,941
Other assets	2,102	1,202
Total assets	$ 27,861	$ 40,488
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,788	$ 377
Accrued expenses	1,721	806
Current portion of operating lease liability	207	178
Total current liabilities	4,716	1,361
Long-term liabilities:		
Operating lease liability	543	659
Commitments and contingencies (Notes 12 and 13)		
Stockholders' equity:		
Preferred Stock, $0.01 par value, 5,000,000 authorized shares, inclusive of the following:		
Series A Junior Participating Preferred Stock, $0.001 par value, 4,000,000 and 250,000 shares authorized as of September 30, 2023, and December 31, 2022, respectively; issued and outstanding - none	—	—
Series B Convertible Preferred Stock, stated value $1,000 per share, 10,000 shares authorized; 690 and 696 issued and outstanding as of September 30, 2023, and December 31, 2022, respectively	690	696
Common Stock, $0.001 par value, authorized shares - 350,000,000; issued and outstanding shares 48,797,450 and 48,084,287 (including 133,333 and 561,104 of unvested stock awards) as of September 30, 2023 and December 31, 2022, respectively	48	48
Additional paid-in capital	418,796	418,270
Accumulated deficit	(396,932)	(380,546)
Total stockholders' equity	22,602	38,468
Total liabilities and stockholders' equity	$ 27,861	$ 40,488

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues:				
Clinical treatment programs - US	$ 46	$ 21	$ 137	$ 85
Total Revenues	46	21	137	85
Costs and Expenses:				
Production costs	30	—	30	—
Research and development	2,734	1,372	7,739	4,883
General and administrative	5,439	5,170	10,280	9,569
Total Costs and Expenses	8,203	6,542	18,049	14,452
Operating Loss	(8,157)	(6,521)	(17,912)	(14,367)
Loss on investments	(310)	(365)	(201)	(1,769)
Interest and other income	294	172	811	296
Gain on sale of fixed assets	39	—	16	—
Redeemable warrants valuation adjustment	—	1	—	35
Gain on sale of income tax operating losses	318	328	900	749
Net Loss	$ (7,816)	$ (6,385)	$ (16,386)	$ (15,056)
Basic and diluted loss per share	$ (0.16)	$ (0.13)	$ (0.34)	$ (0.31)
Weighted average shares outstanding basic and diluted	48,635,165	48,079,210	48,483,802	48,036,559

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
For the Nine months Ended September 30, 2023
(in thousands except share data)
(Unaudited)

For the Three Months Ended September 30, 2023

	Series B Preferred	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance June 30, 2023	$ 690	48,419,491	$ 48	$ 418,513	$ —	$ (389,116)	$ 30,135
Common stock issuance, net of costs	—	377,959	—	233	—	—	233
Equity-based compensation	—	—	—	50	—	—	50
Net comprehensive loss	—	—	—	—	—	(7,816)	(7,816)
Balance September 30, 2023	$ 690	48,797,450	$ 48	$ 418,796	$ —	$ (396,932)	$ 22,602

For the Three Months Ended September 30, 2022

	Series B Preferred	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance June 30, 2022	$ 713	48,048,822	$ 48	$ 417,791	$ —	$ (369,772)	$ 48,780
Common stock issuance, net of costs	—	32,895	—	25	—	—	25
Equity-based compensation	—	—	—	275	—	—	275
Cashless warrant conversion	—	558	—	—	—	—	—
Net comprehensive loss	—	—	—	—	—	(6,385)	(6,385)
Balance September 30, 2022	$ 713	48,082,275	$ 48	$ 418,091	$ —	$ (376,157)	$ 42,695

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
(in thousands except share data)
(Unaudited)

For the Nine Months Ended September 30, 2023

	Series B Preferred	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance December 31, 2022	$ 696	48,084,287	$ 48	$ 418,270	$ —	$ (380,546)	$ 38,468
Common stock issuance, net of costs	—	712,479	—	338	—	—	338
Equity-based compensation	—	—	—	182	—	—	182
Series B preferred shares converted to common shares	(6)	684	—	6	—	—	—
Net comprehensive loss	—	—	—	—	—	(16,386)	(16,386)
Balance September 30, 2023	$ 690	48,797,450	$ 48	$ 418,796	$ —	$ (396,932)	$ 22,602

For the Nine Months Ended September 30, 2022

	Series B Preferred	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance December 31, 2021	$ 715	47,994,672	$ 48	$ 417,217	$ —	$ (361,101)	$ 56,879
Common stock issuance, net of costs	—	86,817	—	80	—		80
Equity-based compensation	—	—	—	792	—	—	792
Cashless warrant conversion	—	558	—	—	—	—	—
Series B preferred shares converted to common shares	(2)	228	—	2	—	—	—
Net comprehensive loss	—	—	—	—	—	(15,056)	(15,056)
Balance September 30, 2022	$ 713	48,082,275	$ 48	$ 418,091	$ —	$ (376,157)	$ 42,695

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Nine months Ended September 30, 2023 and 2022
(in thousands)
(Unaudited)

	2023	2022
Cash flows from operating activities:		
Net loss	$ (16,386)	$ (15,056)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	30	29
Redeemable warrants valuation adjustment	—	(35)
Abandonment of patent and trademark rights	14	—
Amortization of patent, trademark rights	150	57
Non-cash lease expense	151	(717)
Gain on sale of income tax operating losses	(900)	(749)
Equity-based compensation	182	792
Loss on sale of investments	201	1,768
Change in assets and liabilities:		
Other receivables	(9)	—
Funds receivable from New Jersey net operating loss	1,676	1,641
Prepaid expenses and other current assets and other non-current assets	192	(500)
Lease liability	(136)	717
Other assets	—	(73)
Accounts payable	2,411	758
Accrued expenses	915	1,329
Net cash used in operating activities	(11,509)	(10,039)
Cash flows from investing activities:		
Proceeds from sale of marketable investments	924	9,082
Purchase of marketable investments	(1,155)	(1,661)
(Purchase of) Proceeds from sale of property and equipment	(10)	300
Purchase of patent and trademark rights	(377)	(96)
Net cash (used in) provided by investing activities	(618)	7,625
Cash flows from financing activities:		
Proceeds from sale of stock, net of issuance costs	338	80
Net cash provided by financing activities	338	80
Net decrease in cash and cash equivalents	(11,789)	(2,334)
Cash and cash equivalents at beginning of period	27,053	32,093
Cash and cash equivalents at end of period	$ 15,264	$ 29,759
Supplemental disclosures of non-cash investing and financing cash flow information:		
Operating lease liability arising from obtaining right of use asset	$ 49	$ 717
Unrealized loss on marketable investments	$ (71)	$ (1,170)
Conversion of Series B preferred	$ 6	$ 2

See accompanying notes to consolidated financial statements.

AIM IMMUNOTECH INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1: Business and Basis of Presentation

AIM ImmunoTech Inc. and its subsidiaries (collectively, "AIM", "Company", "we" or "us") are an immuno-pharma company headquartered in Ocala, Florida, and focused on the research and development of therapeutics to treat multiple types of cancers, viral diseases and immune-deficiency disorders. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids and natural interferon to enhance the natural antiviral defense system of the human body, and to aid the development of therapeutic products for the treatment of certain cancers and chronic diseases.

AIM's flagship products are Ampligen (rintatolimod), a first-in-class drug of large macromolecular RNA (ribonucleic acid) molecules, and Alferon N Injection (Interferon alfa). Ampligen has not been approved by the FDA or marketed in the United States. Ampligen is approved for commercial sale in the Argentine Republic for the treatment of severe Chronic Fatigue Syndrome ("CFS").

The Company's primary business focus involves Ampligen. Ampligen is a double-stranded RNA ("dsRNA") molecule being developed for globally important cancers, viral diseases and disorders of the immune system.

The Company is currently proceeding primarily in four areas:

- Conducting a randomized, controlled study to evaluate efficacy and safety of Ampligen compared to a control group to treat locally advanced pancreatic cancer patients.
- Evaluating Ampligen in other cancers, as a potential therapy that modifies the tumor microenvironment with the goal of increasing anti-tumor responses to checkpoint inhibitors.
- Exploring Ampligen's antiviral activities and potential use as a prophylactic or treatment for existing viruses, new viruses and mutated viruses thereof.
- Evaluating Ampligen as a treatment for myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS") and fatigue and/or Post-COVID conditions of fatigue.

The Company is prioritizing activities in an order related to the stage of development, with those clinical activities such as pancreatic cancer, ME/CFS and Post-COVID conditions having priority over antiviral experimentation. The Company intends that priority clinical work be conducted in trials authorized by the FDA or European Medicines Agency ("EMA"), which trials support a potential future NDA. However, AIM's antiviral experimentation is designed to accumulate additional preliminary data supporting their hypothesis that Ampligen is a powerful, broad-spectrum prophylaxis and early-onset therapeutic that may confer enhanced immunity and cross-protection. Accordingly, AIM will conduct antiviral programs in those venues most readily available and able to generate valid proof-of-concept data, including foreign venues.

AIM's business plan requires one or more Contract Manufacturing Organizations ("CMO") to produce Ampligen and its Active Pharmaceutical Ingredients (APIs). This includes utilizing Jubilant HollisterStier and Sterling for the manufacture of Ampligen and our Poly I and Poly C12U polynucleotides, respectively. Additionally, our relationship with Polysciences Inc. ("Polysciences") continues and R&D development of polymer manufacture is ongoing.

In the opinion of management, all adjustments necessary for a fair presentation of its consolidated financial statements have been included. Such adjustments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission ("SEC"), and do not contain certain information which will be included in the Company's annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the years ended December 31, 2022, and 2021, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 31, 2023.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure ("GAAP") of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates, and those differences may be material. Accounts requiring the use of significant estimates include determination of other-than-temporary impairment on securities, valuation of deferred taxes, patent and trademark valuations, equity-based compensation calculations, fair value of warrants, and contingency accruals.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants which amounted to 2,763,020 and 2,445,805 are excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2023, and 2022, respectively, since their effect is antidilutive due to the net losses recorded for the periods.

Note 3: Equity-Based Compensation

The 2018 Equity Incentive Plan, effective September 12, 2018, as amended and restated on August 19, 2019 (the "2018 Equity Incentive Plan") authorizes the grant of (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards. Initially, a maximum of 7,000,000 shares of Common Stock were reserved for potential issuance pursuant to awards under the 2018 Equity Incentive Plan. When the plan was amended and restated, an additional 250,000 shares were reserved for potential issuance pursuant to awards under the 2018 Equity Incentive Plan. The number of shares of the Company's common stock available for grant and issuance under the 2018 Equity Incentive Plan is subject to an annual increase on July 1 of each calendar year, by an amount equal to two percent (2%) of the then outstanding shares of the Company's common stock (the "2018 Plan Evergreen Provision"). On July 1, 2019, 2020, 2021, 2022 and 2023, the number of shares of the Company's common stock available for grant and issuance under the 2018 Equity Incentive Plan increased by 44,299 shares, 685,012 shares, 956,660 shares, 960,976 shares and 968,389 shares, respectively. As a result of the 2018 Plan Evergreen Provisions, a maximum of 10,865,336 shares of Common Stock is reserved for potential issuance pursuant to awards under the 2018 Equity Incentive Plan as of January 1, 2023. Unless sooner terminated, the 2018 Equity Incentive Plan will continue in effect for a period of 10 years from its effective date. On October 17, 2018, the Board of Directors (the "Board") issued 26,324 options to the officers and directors at the exercise price of $9.68 expiring in 10 years, and on November 14, 2018, the Board issued 23 options to each employee, officer and director at the exercise price of $9.68 expiring in ten years. On January 28, 2019, 27,570 options were issued to each of these officers with an exercise price of $9.68 for a period of ten years with a vesting period of one year. In August 2020, 400,000 options were issued to each of these officers with an exercise price range of $2.77 to $3.07 for a period of ten years with a vesting period of one year. During the fiscal year ending December 31, 2021, 613,512 options were issued to officers, directors and consultants with an exercise price range of $1.11 to $1.71 for a period of ten years with a vesting period of one year. During the fiscal year ending December 31, 2022, 850,000 options were issued to officers, directors and consultants with an exercise price range of $0.31 to $0.71 for a period of ten years with a vesting period of one year. During the nine months ended September 30, 2023 there have been no options issued.

The fair value of each option and equity warrant award is estimated on the date of grant using a Black-Scholes-Merton option pricing valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option and equity warrant. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. During the nine months ended September 30, 2023, there were no options granted and 300,000 options granted during the nine months ended September 30, 2022.

Employee stock option activity during the three months ended September 30, 2023, was as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value

Outstanding June 30, 2023	2,019,551	$ 3.01	8.36	$ —
Granted	—	—	—	—
Forfeited	—	—	—	—
Expired	(11,113)	2.90	8.41	—
Outstanding September 30, 2023	2,008,438	$ 2.90	8.41	$ —
Vested and expected to vest September 30, 2023	2,008,438	$ 2.90	8.41	$ —
Exercisable September 30, 2023	1,941,772	$ 1.98	6.52	$ —

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested June 30, 2023	166,664	$ 9.17	6.41	$ —
Granted	—	—	—	—
Expired	(11,111)	2.90	8.41	—
Vested	(88,887)	1.98	6.52	—
Unvested September 30, 2023	66,666	$ 14.60	17.04	$ —

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding June 30, 2023	579,032	$ 3.09	8.36	$ —
Granted	—	—	—	—
Forfeited	—	—	—	—
Expired	(53,977)	1.62	8.67	—
Outstanding September 30, 2023	525,055	$ 1.62	8.67	$ —
Vested and expected to vest September 30, 2023	525,055	$ 1.62	8.67	$ —
Exercisable September 30, 2023	458,388	$ 2.99	10.16	$ —

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested June 30, 2023	66,666	$ 9.45	4.59	$ —
Granted	—	—	—	—
Expired	(54,100)	1.62	8.67	—
Vested	54,101	2.99	10.16	—
Unvested September 30, 2023	66,667	$ 6.75	4.28	$ —

Equity-based compensation expense was approximately $50,000 and $275,000 for the three months ended September 30, 2023 and 2022, respectively.

Employee stock option activity during the nine months ended September 30, 2023, was as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2023	2,020,214	$ 3.01	8.86	$ —
Granted	—	—	—	—
Forfeited	—	—	—	—
Expired	(11,776)	2.90	12.81	—
Outstanding September 30, 2023	2,008,438	$ 2.90	8.41	$ —
Vested and expected to vest September 30, 2023	2,008,438	$ 2.90	8.41	$ —
Exercisable September 30, 2023	1,941,772	$ 1.98	6.52	$ —

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2023	392,326	$ .80	8.86	$ —
Granted	—	—	—	—
Expired	(11,776)	2.90	8.41	—
Vested	(313,884)	1.98	6.52	—
Unvested September 30, 2023	66,666	$ 14.60	17.04	$ —

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2023	579,155	$ 3.09	7.93	$ —
Granted	—	—	—	—
Forfeited	—	—	—	—
Expired	(54,100)	1.62	8.67	—

Outstanding September 30, 2023	525,055	$ 1.62	8.67	$ —
Vested and expected to vest September 30, 2023	525,055	$ 1.62	8.67	$ —
Exercisable September 30, 2023	458,388	$ 2.99	10.16	$ —

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2023	166,789	$ 4.05	9.49	$ —
Granted	—	—	—	—
Expired	(54,223)	1.62	8.67	—
Vested	(45,899)	2.99	10.16	—
Unvested September 30, 2023	66,667	$ 6.75	4.28	$ —

Equity-based compensation expense was approximately $182,000 and $792,000 for the nine months ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, and 2022, there was approximately $35,000 and $179,000, respectively, of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan. As of the fourth quarter 2023, there will be no unrecognized equity-based compensation.

Note 4: Marketable Investments

Marketable investments consist of mutual funds. As of September 30, 2023 and December 31, 2022, it was determined that none of the marketable investments had an other-than-temporary impairment. As of September 30, 2023 and December 31, 2022, all securities were measured as Level 1 instruments of the fair value measurements standard (See Note 11: Fair Value). As of September 30, 2023, and December 31, 2022 the Company held $7,167,000 and $7,137,000 in mutual funds, respectively.

Mutual Funds classified as available for sale consisted of:

	September 30, 2023 (in thousands)	
Securities	Fair Value	Short-Term Investments
Mutual Funds	$ 7,167	$ 7,167
Totals	$ 7,167	$ 7,167

Securities	**For the Three months Ended September 30, 2023** (in thousands)
Net losses recognized during the period on equity securities	$ (309)
Less: Net gains and losses recognized during the period on equity securities sold during the period	(42)
Unrealized gains and losses recognized during the reporting period on equity securities still held at the reporting date	$ (267)

Securities	For the Nine months Ended **September 30, 2023** (in thousands)

Net losses recognized during the period on equity securities	$	(201)
Less: Net gains and losses recognized during the period on equity securities sold during the period		(130)
Unrealized gains and losses recognized during the reporting period on equity securities still held at the reporting date	$	(71)

Mutual Funds classified as available for sale consisted of:

Securities	December 31, 2022 (in thousands) Fair Value	Short-Term Investments
Mutual Funds	$ 7,137	$ 7,137
Totals	$ 7,137	$ 7,137

Securities	**For the Three months Ended September 30, 2022** (in thousands)
Net losses recognized during the period on equity securities	$ (365)
Less: Net gains and losses recognized during the period on equity securities sold during the period	(15)
Unrealized gains and losses recognized during the reporting period on equity securities still held at the reporting date	$ (350)

Securities	For the Nine months Ended September 30, 2022 (in thousands)
Net losses recognized during the period on equity securities	$ (1,768)
Less: Net gains and losses recognized during the period on equity securities sold during the period	(598)
Unrealized gains and losses recognized during the reporting period on equity securities still held at the reporting date	$ (1,170)

Note 5: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands) September 30, 2023	December 31, 2022
Compensation	$ 29	$ 1
Professional fees	1,459	492
Clinical trial expenses	127	110
Other expenses	106	203
	$ 1,721	$ 806

Note 6: Property and Equipment, net

	(in thousands) September 30, 2023	December 31, 2022
Furniture, fixtures, and equipment	1,555	2,233
Less: accumulated depreciation	(1,419)	(2,038)
Property and equipment, net	$ 136	$ 195

Property and equipment are recorded at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, ranging from three to ten years. Depreciation expense for the nine months ending September 30, 2023 and September 30, 2022 was $30,000 and $29,000, respectively.

Note 7: Patents, and Trademark Rights, Net

The table below presents the changes in patent and trademark rights (in thousands):

December 31, 2022	$ 1,941

Acquisitions		377
Abandonments and expirations		(14)
Amortization		(150)
September 30, 2023	$	2,154

Patents and trademarks are stated at cost. Patents and trademarks are amortized using the straight-line method over an estimated useful life of 17 years and 10 years, respectively.

Amortization of patents and trademarks for each of the next five years and thereafter is as follows (in thousands):

Year Ending December 31,		
2023	$	58
2024		225
2025		217
2026		215
2027		194
Thereafter		1,245
Total	$	2,154

Note 8: Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of $0.01 par value preferred stock with such designations, rights and preferences as may be determined by the Board. Of our authorized preferred stock, 4,000,000 shares have been designated as Series A Junior Participating Preferred Stock and 10,000 shares have been designated as Series B Convertible Preferred Stock.

Series A Junior Participating Preferred Stock

On May 10, 2023, the Company filed a Certificate of Increase in Delaware, increasing the number of preferred stock designated as Series A Junior Participating Preferred Stock to 4,000,000 from 250,000 shares.

Series B Convertible Preferred Stock

The series of preferred stock shall be designated as its Series B Convertible Preferred Stock (the "Preferred Stock") and the number of shares so designated shall be up to 10,000. Each share of Preferred Stock shall have a par value of $0.01 per share and a stated value equal to $1,000 (the "Stated Value"). The shares of Preferred Stock shall initially be issued and maintained in the form of securities held in book-entry form and the Depository Trust Company or its nominee ("DTC") shall initially be the sole registered holder of the shares of Preferred Stock.

Each share of Preferred Stock shall be convertible, at any time and from time to time from and after the Original Issue Date at the option of the Holder thereof or at any time and from time to time on or after the second anniversary of the Original Issue Date at the option of the Corporation, into that number of shares of Common Stock (subject in each case to the limitations determined by dividing the Stated Value of such share of Preferred Stock by the Conversion Price). The conversion price for the Preferred Stock shall be equal to $0.20, subject to adjustment herein (the "Conversion Price").

Pursuant to a registration statement relating to a rights offering declared effective by the SEC on February 14, 2019, AIM distributed to its holders of common stock and to holders of certain options and redeemable warrants as of February 14, 2019, at no charge, one non-transferable subscription right for each share of common stock held or deemed held on the record date.

Each right entitled the holder to purchase one unit, at a subscription price of $1,000 per unit, consisting of one share of Series B Convertible Preferred Stock with a face value of $1,000 (and immediately convertible into common stock at an assumed conversion price of $8.80) and 114 warrants with an assumed exercise price of $8.80. The redeemable warrants are exercisable for five years after the date of issuance. The net proceeds realized from the rights offering were approximately $4,700,000. During the nine months ending September 30, 2023, 6 shares of Series B Convertible Preferred Stock were converted into common stock.

As of September 30, 2023, and December 31, 2022, the Company had 690 and 696 shares of Series B Convertible Preferred Stock outstanding, respectively. Holders shall be entitled to receive, and the Company shall pay, dividends on shares of Series B Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividend actually paid on shares of Common Stock when as and if such dividends are paid on shares of the Common Stock. Each such Preferred Share is convertible into 114 shares of common stock. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Holders shall be entitled to receive out of the assets, whether capital or surplus of the Company the same amount that a holder of Common Stock would receive if the Preferred Stock was fully converted. The Series B Convertible Preferred Stock does not carry voting Rights.

(b) Common Stock and Equity Finances

The Company has authorized shares of 350,000,000 with specific limitations and restrictions on the usage of 8,000,000 of the 350,000,000 authorized shares. As of September 30, 2023, and December 31, 2022, there were 48,797,450 and 48,084,287 shares of Common Stock issued and outstanding, respectively.

Employee Stock Purchase Plan (Not equity compensation)

On July 7, 2020, the Board approved a plan pursuant to which all directors, officers, and employees could purchase from the Company up to an aggregate of $500,000 worth of shares at the market price (including subsequent plans, the “Employee Stock Purchase Plan”). Pursuant to NYSE American rules, this plan was effective for a sixty-day period commencing upon the date that the NYSE American approved the Company’s Supplemental Listing Application. The Company created successive new plans following the expiration of the July 7, 2020 plan. The latest plan was approved by the Board in October 2023 and expires January 2,2024.

During the nine months ended September 30, 2023, the Company issued a total of 385,424 shares of its common stock at a price ranging from $0.31 to $0.67 for total proceeds of $135,000 as part of the employee stock purchase plan.

During the nine months ended September 30, 2022, the Company issued a total of 87,045 shares of its common stock at prices ranging from $0.72 to $1.02 for total proceeds of $80,000 as part of the employee stock purchase plan.

Warrants (Rights offering)

On September 27, 2019, the Company closed a public offering underwritten by A.G.P./Alliance Global Partners, LLC (the “Offering”) of (i) 1,740,550 shares of Common Stock; (ii) pre-funded warrants exercisable for 7,148,310 shares of Common Stock (the “Pre-funded Warrants”), and (iii) warrants to purchase up to an aggregate of 8,888,860 shares of Common Stock (the “Warrants”). In conjunction with the Offering, we issued a Representative’s Warrant to purchase up to an aggregate of 266,665 shares of common stock (the “Representative’s Warrant”). The shares of Common Stock and Warrants were sold at a combined Offering price of $0.90, less underwriting discounts and commissions. Each Warrant sold with the shares of Common Stock represents the right to purchase one share of Common Stock at an exercise price of $0.99 per share. The Pre-Funded Warrants and Warrants were sold at a combined Offering price of $0.899, less underwriting discounts and commissions. The Pre-Funded Warrants were sold to purchasers whose purchase of shares of Common Stock in the Offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the Company’s outstanding Common Stock immediately following the consummation of the Offering, in lieu of shares of Common Stock. Each Pre-Funded Warrant represents the right to purchase one share of Common Stock at an exercise price of $0.001 per share. The Pre-Funded Warrants are exercisable immediately and may be exercised at any time until the Pre-Funded Warrants are exercised in full. A registration statement on Form S-1, relating to the Offering was filed with the SEC and was declared effective on September 25, 2019, the net proceeds were approximately $7,200,000. During the year ending December 31, 2020, 1,870,000 of the Pre-funded Warrants were exercised and 8,873,960 Warrants were exercised. In addition, on March 25, 2020, the Representative’s Warrant was amended to permit exercise of such warrant to commence on March 30, 2020. These warrants were exercised on March 31, 2020 and an aggregate of 266,665 shares were issued upon exercise of this warrant for gross proceeds of approximately $264,000 and a $46,000 expense for the warrant modification. As of September 30, 2023, there are 15,000 Warrants outstanding.

Equity Distribution Agreement

On April 19, 2023, the Company entered into an Equity Distribution Agreement (the “EDA”) with Maxim Group LLC (“Maxim”), pursuant to which the Company may sell, from time to time, shares of its common stock having an aggregate offering price of up to $8.5 million through Maxim, as agent (the “Offering”). Sales under the EDA were registered under the S-3 Shelf Registration Statement. Under the terms of the EDA, Maxim will be entitled to a transaction fee at a fixed rate of 3.0% of the gross sales price of shares sold under the EDA. For the nine months ended September 30, 2023, the Company sold 327,055 shares under the EDA for total gross proceeds of approximately $209,000, which includes a 3.0% fee to Maxim of $6,271.

Rights Plan

On May 12, 2023, the Company amended and restated its November 14, 2017 Rights Plan with American Stock Transfer & Trust Company as Rights Agent (the “Rights Plan”).

Note 9: **Cash and Cash Equivalents**

AIM considers all highly liquid interest-earning investments with an original maturity of three months or less at the date of purchase to be cash equivalents.

Note 10: Recent Accounting Pronouncements

The Company has implemented all new accounting pronouncements that are in effect. These pronouncements did not have any material impact on the financial statements unless otherwise disclosed, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations. Accounting pronouncements issued by the FASB since filing the Annual Report on Form 10-K for the year ended December 31, 2022 did not or are not believed by management to have a material impact on the Company’s present or future financial statements.

Note 11: Fair Value

Fair Value

The Company complies with the provisions of FASB ASC 820 “Fair Value Measurements” for its financial and non-financial assets and liabilities. ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis.

The Company accounts for certain assets and liabilities at fair value. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. AIM categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

1. Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date. Generally, this includes debt and equity securities that are traded in an active market.
2. Level 2 – Observable inputs other than Level 1 prices such as quote prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.
3. Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of September 30, 2023, the Company has classified the warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing the warrants.

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as (in thousands):

	As of September 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalent	$ 14,110	$ 14,110	$ —	$ —
Marketable investments	$ 7,167	$ 7,167	$ —	$ —

	As of December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalent	$ 25,180	$ 25,180	$ —	$ —
Marketable investments	$ 7,137	$ 7,137	$ —	$ —

The Company’s cash balances are representative of their fair values as these balances are comprised of deposits available on demand. For certain instruments, including funds receivable from New Jersey net operating loss, accounts payable and accrued expenses, it was estimated that the carrying values approximated the fair value due to the short-term maturities of these instruments (Level 1).

The Company also has certain redeemable warrants with a cash settlement feature in the occurrence of a Fundamental Transaction. The fair value of the redeemable warrants ("Redeemable Warrants") related to the Company's April 2018 and March 2019 common stock and warrant issuance, are calculated using a Monte Carlo Simulation (Level 3).

The Company recomputes the fair value of the Redeemable Warrants at the issuance date and the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If the Company were to alter its assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

The Company utilized the following assumptions to estimate the fair value of the April 2018 Redeemable Warrants:

	September 30, 2023	December 31, 2022
Underlying price per share	$ 0.46	$ 0.31
Exercise price per share	$ 17.16	$ 17.16
Risk-free interest rate	5.55%	4.74%
Expected holding period	0.07	0.81
Expected volatility	85%	75%
Expected dividend yield	—	—

The Company utilized the following assumptions to estimate the fair value of the March 2019 Redeemable Warrants:

	September 30, 2023	December 31, 2022
Underlying price per share	$ 0.46	$ 0.31
Exercise price per share	$ 8.80	$ 8.80
Risk-free interest rate	5.53%	4.67%
Expected holding period	0.44	1.19
Expected volatility	80%	70%
Expected dividend yield	—	—

The significant assumptions using the Monte Carlo Simulation approach for valuation of the Warrants are:

(i) *Risk-Free Interest Rate*. The risk-free interest rates for the Warrants are based on U.S. Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.

(ii) *Expected Holding Period*. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.

(iii) *Expected Volatility*. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.

(iv) *Expected Dividend Yield*. The expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is 0% and this assumption will be continued in future calculations unless the Company changes its dividend policy.

(v) *Expected Probability of a Fundamental Transaction.* Put rights arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is unlikely because:

1. The Company only has one product that is FDA approved but is currently not available for commercial sales.
2. The Company will have to perform additional clinical trials for FDA approval of its flagship product.
3. Industry and market conditions continue to include uncertainty, adding risk to any transaction.
4. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development.
5. The Company has minimal revenues streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and
6. The Company's Rights Agreement and Executive Agreements make it less attractive to a potential buyer.

With the above factors utilized in analysis of the likelihood of the Put's potential Liability, the Company estimated the range of probabilities related to a Put right being triggered as:

Range of Probability	Probability
Low	0.5%
Medium	1.0%
High	5.0%

The Monte Carlo Simulation has incorporated a 5.0% probability of a Fundamental Transaction to date for the life of the securities.

(vi) *Expected Timing of Announcement of a Fundamental Transaction.* As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.

(vii) *Expected 100 Day Volatility at Announcement of a Fundamental Transaction.* An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Redeemable Warrants' grant dates, with a floor of 100%, were utilized as a proxy for future volatility estimates.

(viii) *Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction*. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Redeemable Warrant expiration date for each simulation.

(ix) *Expected Time Between Announcement and Consummation of a Fundamental Transaction.* The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers and is estimated to be nine months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the actual historical prices input for the relevant period input change. As of September 30, 2023 and December 31, 2022 there was no carrying amount and estimated fair value of the above Redeemable Warrants.

Note 12: Leases

The Company leases office and storage space, and other equipment under non-cancellable operating leases with initial terms typically ranging from 1 to 5 years.

At contract inception, utilizing the guidance of ASC 842 "*Leases*" the Company reviews the facts and circumstances of each contract to determine its proper treatment and classification in accordance with U.S. GAAP.

The Company has elected to include both lease and non-lease components in the determination of lease payments. Payments made to a lessor for items such as taxes, insurance, common area maintenance, or other costs commonly referred to as executory costs, are also included in lease payments if they are fixed. The fixed portion of these payments are included in the calculation of the lease liability, while any variable portion is recognized as variable lease expenses as incurred.

At lease inception, lease-related assets and liabilities are measured at the present value of future lease payments over the lease term. For leases that do not provide an implicit rate, the Company utilizes an estimated incremental borrowing rate based on market observations existing at lease inception to calculate the present value of future payments.

Leased assets are disclosed as Right of Use assets on the Company's consolidated balance sheet and are amortized over the expected useful life of the lease. Lease liabilities are separately disclosed as a current and non-current portion on the Company's consolidated balance sheet.

Short term leases with an initial term of 12 months or less are not presented on the balance sheet with expense recognized as incurred.

The Company entered into a Lease Agreement for a term of five years commencing on September 14, 2020 pursuant to which the Company agreed to lease two Sharp copiers. The base rent under the agreement is $1,415 per month.

On June 13, 2018, the Company entered into a Lease Agreement for a term of six years commencing on July 1, 2018 pursuant to which the Company agreed to lease approximately 3,000 rentable square feet. The base rent increases by 3% each year, and ranges from $2,100 per month for the first year to $2,785 per month for the sixth year.

On May 1, 2019, the Company entered into a Lease Agreement for a term of three years commencing on May 1, 2019, pursuant to which the Company agreed to lease approximately 3,000 rentable square feet at a base rent of $2,500 per month. The Company renewed the lease for a one-year term extending the rental period to April 2023. On October 5, 2022, the Company renewed the lease for an additional one-year term at a monthly cost of $2,850 that commenced on May 1, 2023. On October 6, 2023, the Company renewed the lease for an additional one-year term at a monthly cost of $3,000 that commences on May 1, 2024, extending the lease through April 30, 2025.

On February 17, 2022, the Company entered into a Lease Agreement for a term of two years commencing on March 1, 2022, pursuant to which the Company agreed to lease a Canon copier. The base rent is $322 per month for the term of the lease.

On June 16, 2022, the Company entered into a Lease Agreement for a term of five years commencing on July 1, 2022 pursuant to which the Company agreed to lease approximately 5,210 rentable square feet. The base rent increases by 3% each year, and ranges from $15,630 per month for the first year to $18,118 per month for the fifth year.

On December 9, 2022, the Company entered into a Lease Agreement for a term of two years commencing on April 1, 2023, pursuant to which the Company agreed to lease approximately 470 square feet of wet laboratory space. The base rent increases by 6% each year and ranges from $1,645 per month for the first year to $1,744 per month for the second year.

The expected lease term includes both contractual lease periods and, when applicable, cancelable option periods when it is reasonably certain that the Company would exercise such options. The Company's leases have remaining lease terms between 9 and 50 months. As of September 30, 2023, and December 31, 2022, the weighted-average remaining term was 43 and 42 months, respectively.

The Company's weighted average incremental borrowing rate for its leases was 10% as of September 30, 2023, and December 31, 2022, respectively.

Future minimum lease payments as of September 30, 2023, are as follows (in thousands):

Year Ending December 31,		
2023	$	73
2024		264
2025		221
2026		200
2027		133
Less imputed interest		(141)
Total	$	750

As of September 30, 2023, and December 31, 2022, the balance of the right of use assets was $727,000 and $829,000, respectively, and the corresponding lease liability balance was $750,000 and $837,000, respectively. Total rent expense for the nine months ended September 30, 2023, and September 30, 2022, was $230,000 and 75,000, respectively. Total rent expense for short term leases for the nine months ended September 30, 2023, and September 30, 2022, was $198,000, and $8,000, respectively, included as general and administrative expense.

Note 13: Research, Consulting and Supply Agreements

The following represent companies with which AIM has active contracts that it paid toward during the nine months ended September 30, 2023.

Amarex Clinical Research LLC

AIM has multiple contracts with Amarex Clinical Research LLC ("Amarex"). During the nine months ended September 30, 2023, the Company paid $1,266,800 related to these ongoing agreements:

- Pancreatic Cancer - In April 2022, AIM executed a work order with Amarex pursuant to which Amarex is managing a Phase 2 clinical trial in locally advanced pancreatic cancer patients designated AMP-270. Per the work order, AIM anticipates that Amarex's management of the study will cost approximately $8.4 million. This estimate includes pass-through costs of approximately $1.0 million and excludes certain third-party and investigator costs and escalations necessary for study completion. AIM anticipates that the study will take approximately 4.6 years to complete.
  - During the nine months ended September 30, 2023, the Company paid approximately $350,600 related to this agreement.
- Post-COVID Conditions - On September 13, 2022, AIM executed a work order with Amarex, pursuant to which Amarex is managing a Phase 2 trial in patients with Post-COVID Conditions. AIM is sponsoring the study. AIM anticipates that the study will cost approximately $6.4 million, which includes pass through costs of approximately $125,470, investigator costs estimated at about $4.4 million, and excludes certain other third-party costs and escalations.
  - During the nine months ended September 30, 2023, the Company paid approximately $916,200 related to this agreement.

hVIVO Services Limited

In July 2021, the Company executed a Reservation and Start-Up Agreement (the "Agreement") with hVIVO Services Limited ("hVIVO"), and subsequently signed a clinical trial agreement ("CTA") in September. For the year ended December 31, 2021, the Company incurred an expense and paid hVIVO approximately $2,340,000 for services incurred in 2021. In March 2022, the Company announced that it had officially withdrawn its application from the Medicines and Healthcare Regulatory Agency and terminated its agreement with hVIVO and incurred a cancelation fee of $60,000 which was paid in the first quarter 2022.

Impatients N.V.

In 2016, the Company entered into a five-year agreement (the "Impatients Agreement") with Impatients, N.V. ("myTomorrows"), a Netherlands-based company, for the commencement and management of an EAP in Europe and Turkey (the "Territory") related to ME/CFS. Pursuant to the agreement, myTomorrows, as exclusive service provider and distributor in the Territory, is performing EAP activities. The agreement was automatically extended for a period of 12 months on May 20, 2021; has been automatically extended for 12 months on each subsequent May 20; and will continue to be automatically extended for periods of 12 months every May 20 until terminated or the terms of the agreement are met.

- During the nine months ended September 30, 2023, the Company paid approximately $31,100 related to this agreement.

Jubilant HollisterStier

Jubilant HollisterStier ("Jubilant") is AIM's authorized CMO for Ampligen for the approval in Argentina. In 2017, the Company entered into an agreement with Jubilant pursuant to which Jubilant will manufacture batches of Ampligen® for the Company. Since the 2017 engagement of Jubilant, two lots of Ampligen consisting of more than 16,000 units were manufactured and released in the year 2018. The first lot was designated for human use in the United States in the cost recovery CFS program and for expanded oncology clinical trials. The second lot has been designated for these programs in addition to commercial distribution in Argentina for the treatment of CFS. Jubilant manufactured additional two lots of Ampligen in December 2019 and January 2020. In March 2023, the Company submitted a purchase order for a total of $1,432,257 to manufacture additional lots of Ampligen at Jubilant.

- During the nine months ended September 30, 2023, the Company paid approximately $1,432,300 related to this agreement.

Pharmaceutics International Inc.

In December 2020, AIM added Pharmaceutics International Inc. ("Pii") as a "Fill & Finish" provider to enhance AIM's capacity to produce the drug Ampligen. This addition amplifies AIM's manufacturing capability by providing redundancy and cost savings. The contracts augment AIM's existing fill and finish capacity. As agreed to in the Master Services Agreement, the terms of each of AIM's projects with Pii will be negotiated separately and defined in individual Service Contracts. For the year ended December 31, 2022, the Company had incurred an expense and paid Pii approximately $278,000.

- During the nine months ended September 30, 2023, the Company paid approximately $55,400 related to this agreement.

Polysciences Inc.

In April 2021, AIM approved a proposal from Polysciences Inc. ("Polysciences") for the manufacture of our Poly I and Poly C12U polynucleotides and associated test methods at Polysciences' Warrington, PA location to enhance our capacity to produce the polymer precursors to the drug Ampligen. The Company is working with Polysciences to negotiate and finalize both a Service Agreement and a Quality Agreement. For the year ended December 31, 2021, the Company incurred an expense and paid Polysciences approximately $250,000.

- During the nine months ended September 30, 2023, there were no payments related to this agreement.

Yamasa Corporation

AIM also utilizes Yamasa Corporation ("Yamasa") for the production of raw materials required to create polymer precursors to manufacture the drug Ampligen. In March 2023, the Company submitted a work order for $327,730 related to the purchase of raw materials from Yamasa. These raw materials will be used in the manufacture of polymer precursors at Sterling.

- During the nine months ended September 30, 2023, there were no payments related to this agreement.

Sterling Pharma Solutions

On December 5, 2022, the Company entered into a Master Service Agreement and a Quality Agreement with Sterling Pharma Solutions ("Sterling") for the manufacture of the Company's Poly I and Poly C12U polynucleotides and transfer of associated test methods at Sterling's Dudley, UK location to produce the polymer precursors to manufacture the drug Ampligen.

- During the nine months ended September 30, 2023, the Company paid approximately $357,000 related to this agreement.

Note 14: Subsequent Events

In the Company's lawsuit against BioLife Plasma Services, LP, the trial court issued a ruling in March 2023 on cross Motions for Summary Judgment in which it denied all of the Company's motions and granted defendant's Motion to exclude evidence of future loss of profit damages. The ruling specified that AIM had properly pled and the Court was specifically allowing AIM's damages theory to proceed on reliance damages. The Company sought reconsideration of the ruling based on its internal inconsistency with the contemporaneously issued Order which allowed only the counterclaims to proceed. In July, the Company sought appellate review of the inconsistent lower Court pretrial rulings. On September 8, 2023, the Court issued an Order in response to the Motion for Reconsideration. The Court granted the Motion, vacated its prior Order on summary judgment, and issued a new Order and Opinion. The new Order and Opinion again denied the motion for summary judgment in total, and granted the motion for summary judgment of defendants. The effect of the Order was to once again allow only the defendant's counterclaim to proceed. On October 6, 2023, the Company sought a certification of the Court to allow immediate appeal. The Court has not ruled on the Motion.

On August 8, 2023, the Company filed a motion to reconsider its lawsuit against Robert Chioini, Todd Deutsch, Jonathan Jorgl, Ted D. Kellner, Walter Lautz, Michael Rice and Franz Tudor in the Federal District Court for the Middle District of Florida (the "Federal Securities Action"). The court had dismissed the Federal Securities Action on July 10, 2023 on mootness grounds because the 2022 Annual Meeting, including the election of directors, had already occurred. The Company filed a motion for the district court to reconsider the dismissal of the Federal Securities Action. The district court denied its motion to reconsider on September 27, 2023. Separately, Mr. Lautz moved for reconsideration of the district court's order pursuant to the Private Securities Litigation Reform Act of 1995 on August 7, 2023, and Mr. Jorgl moved for attorneys' fees under Rule 11 on September 12, 2023. On October 10, 2023, the district court granted-in-part Mr. Lautz's motion, postponed ruling on Mr. Jorgl's motion and scheduled a hearing on November 2, 2023. However, after the Company filed a notice of appeal on October 27, 2023, the district court canceled the November 2, 2023 hearing and ordered the parties to meet and confer on preparing a joint statement addressing whether (1) the district court retained subject matter jurisdiction over Messrs. Lautz and Jorgl's motions and (2) judicial economy counsels in favor of postponing a ruling on Messrs. Lautz and Jorgl's motions pending our appeal.

On August 25, 2023, Ted D. Kellner filed suit against the Company and the members of its Board in the Delaware Court of Chancery (the "2023 Delaware Litigation"). The complaint challenged (1) the Company's adoption of amendments to the advance notice provision of its bylaws; and (2) the decision of the Board to reject Kellner's notice of intent to nominate himself and two other candidates for election to the Board at the Company's 2023 annual meeting of stockholders on the basis that the nomination notice failed to comply with the Company's amended bylaws. The complaint seeks, among other things, a declaration that (1) the amendments to the Company's bylaws were unlawful; and/or (2) the Board's application of the amended bylaws to reject Kellner's nomination notice was unlawful or inequitable. On September 11, 2023, the Company and the members of the Board filed an answer responding to Kellner's complaint and filed a counterclaim. The counterclaim seeks a declaration that (1) the Company's bylaw amendments are lawful and valid; and (2) Kellner's nomination notice did not comply with the Company's bylaws.

Upon completion of expedited discovery and briefing, the Delaware Court of Chancery held trial from October 30, 2023 to November 1, 2023. Post-trial briefs from both parties are due on November 16, 2023, and post-trial argument is scheduled for November 21, 2023. An opinion is expected before the Company's 2023 annual meeting of stockholders, scheduled to convene on December 1, 2023. Although Kellner is not presently seeking monetary relief of legal fees from the Company in the 2023 Delaware Litigation, if elected, his slate of purported director nominees intends to seek to reimburse Kellner and related parties' legal fees and expenses incurred during their 2022 and 2023 proxy contests.

On July 20, 2023, the Company and the Board, as the defendants, filed a motion to shift all litigation fees they incurred in connection with the Jorgl v. AIM Immunotech, Inc. et al. action to Jorgl on the basis that he brought the litigation in bad faith (the "AIM Fee Motion"). Also on July 20, 2023, Jorgl filed a motion to shift certain legal fees to the defendants that he incurred in connection with contesting a subpoena defendants served on the legal counsel that advised Jorgl in his nomination efforts, Baker & Hostetler LLP (the "Jorgl Fee Motion"). The Delaware Court of Chancery recently ruled on certain discovery motions pertaining to the AIM Fee Motion, and the parties will be negotiating a briefing schedule to complete briefing on the AIM Fee Motion and the Jorgl Fee Motion.

On October 16, 2023, AIM entered into an agreement with Azenova, LLC ("Azenova"), a professional business development (BD) consulting firm, to assist AIM with its BD efforts with the goal of entering into a partnership, out-license or other transaction whereby a biopharmaceutical company takes on the further development and commercialization of Ampligen with the goal of maximizing value to AIM.

On October 26, 2023, by unanimous consent, the Board approved the latest Employee Stock Purchase Plan pursuant to which all directors, officers, and employees could purchase from the Company up to an aggregate of $500,000 worth of shares at

the market price.

ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations

Special Note Regarding Forward-Looking Statements

Certain statements in this Report contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in this Report in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations"; Part II, Item 1. "Legal Proceedings"; and Part II, Item 1A. "Risk Factors", as well as the following sections of our Annual Report on Form 10-K for the year ended December 31, 2022: Item 1. "Business", Part I; Item 1A. "Risk Factors", Part I; Item 3. "Legal Proceedings", Part I and Part II; Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations".

All statements, other than statements of historical fact, included or incorporated herein regarding our strategy, future operations, financial position, future revenues, projected costs, plans, prospects and objectives are forward-looking statements. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "think," "may," "could," "will," "would," "should," "continue," "potential," "likely," "opportunity" and similar expressions or variations of such words are intended to identify forward-looking statements but are not the exclusive means of identifying forward-looking statements and their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects as we will need additional funding to proceed with our objectives; the potential therapeutic effect of our products; the possibility of obtaining regulatory approval; our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms; our ability to manufacture and sell any products; our ability to enter into arrangements with third party vendors; market acceptance of our products; our ability to earn a profit from sales or licenses of any drugs; our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry.

We are in various stages of seeking to determine whether Ampligen will be effective in the treatment of multiple types of viral diseases, cancers, and immune-deficiency disorders. We discuss in this Report our current and anticipated future activities, all of which are subject to change for a number of reasons. Significant testing and trials will be required to determine whether Ampligen will be effective in the treatment of these conditions. Results obtained in animal models do not necessarily predict results in humans. Human clinical trials will be necessary to prove whether or not Ampligen will be efficacious in humans. No assurance can be given as to whether current or planned clinical trials will be successful or yield favorable data and the trials are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the institutions sponsoring other trials. We cannot assure that the clinical studies will be successful or yield any useful data or require additional funding.

In February 2013, we received a Complete Response Letter (CRL) from the Food and Drug Administration, or FDA, for our Ampligen New Drug Application, or NDA, for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. Accordingly, the remaining steps to potentially gain FDA approval of the Ampligen NDA, the final results of these and other ongoing activities could vary materially from our expectations and could adversely affect the chances for approval of the Ampligen NDA. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) the FDA may ask for additional data, information or studies to be completed or provided; and (ii) the FDA may require additional work related to the commercial manufacturing process to be completed or may, in the course of the inspection of manufacturing facilities, identify issues to be resolved. A proposed confirmatory trial and responses to the CRL are being worked on now by our R&D team and consultants.

In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica ("ANMAT"), for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe, but cannot assure, that this approval provides a platform for potential sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program, or EAP, as discussed below and underway in Europe in pancreatic cancer. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina

for the commercial launch and subsequent sales. In June 2020, we received import clearance from ANMAT to import the first shipment of commercial-grade vials of Ampligen into Argentina. We are currently working with GP Pharma on the commercial launch of Ampligen in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch and ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is ongoing due to ANMAT's internal processes. Approval of rintatolimod for severe CFS in the Argentine Republic does not in any way suggest that the Ampligen NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an EAP in Europe and Turkey related to CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in this territory, is performing EAP activities. In January 2017, the EAP was extended to pancreatic cancer patients beginning in the Netherlands. In February 2018, we signed an amendment to extend the territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of CFS. MyTomorrows provides services related to the supply and distribution of Ampligen to patients in Early Access Programs (EAPs) which are initiated through a physician's request; there have been no physician requests that have led to government approval, therefore no patients have been treated under an EAP for either pancreatic cancer or CFS in Canada. No assurance can be given that we can sufficiently supply product should we experience an unexpected demand for Ampligen in our clinical studies, the commercial launch in Argentina or pursuant to the EAPs. No assurance can be given that Ampligen will prove effective in the treatment of pancreatic cancer. The agreement was automatically extended for a period of 12 months on May 20, 2021; has been automatically extended for 12 months on each subsequent May 20; and will continue to be automatically extended for periods of 12 months every May 20 until terminated or the terms of the agreement are met.

Multiple Ampligen clinical trials are underway, in various phases of development and activity, with subjects enrolled at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint blockade. One site of clinical trials is Roswell Park and the other is the University of Pittsburgh Medical Center. (See: "Research and Development; Immuno-oncology"). No assurance can be given as to the results of these underway trials. No assurance can be given as to whether some or all of the planned additional oncology clinical trials will occur and they are subject to many factors, including lack of regulatory approval(s), lack of study drug, or a change in priorities at the sponsoring universities or cancer centers. Even if these additional clinical trials are initiated, as we are not the sponsor, we cannot assure that these clinical studies or the studies underway will be successful or yield any useful data. In addition, initiation of planned clinical trials may not occur secondary to many factors including lack of regulatory approval(s) or lack of study drug.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen in the United States and abroad as well as seeking to broaden commercial therapeutic indications for Alferon N Injection presently approved in the United States and Argentina. We continue to pursue senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms. Our ability to commercialize our products, widen commercial therapeutic indications of Alferon N Injection and/or capitalize on our collaborations with research laboratories to examine our products are subject to a number of significant risks and uncertainties including, but not limited to our, ability to enter into more definitive agreements with some of the research laboratories and others that we are collaborating with, to fund and conduct additional testing and studies, whether or not such testing is successful or requires additional testing and meets the requirements of the FDA and comparable foreign regulatory agencies. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

We strived to maximize the outsourcing of certain components of our manufacturing, quality control, marketing and distribution while maintaining control over the entire process through our quality assurance and regulatory groups. We cannot provide any guarantee that the facility or our contract manufacturers will pass an FDA pre-approval inspection for Alferon N Injection manufacturing.

In May 2021, we exercised our option to re-purchase the New Brunswick manufacturing facility, pursuant to the terms of the March 2018 sale and lease-back agreement. We thereafter sold certain equipment and machinery that we determined to be obsolete and no longer needed for current or future manufacturing. On March 3, 2022, we entered into an Agreement of Sale and Purchase with Acellories, Inc. to purchase the property for an estimated $3.9 million. The sale was finalized on November 1, 2022, for $3.7 million net of normal closing cost.

In June 2022 we entered into a lease agreement with the New Jersey Economic Development Authority for a 5,210 square-foot, state-of-the-art R&D facility at the New Jersey Bioscience Center ("NJBC"), primarily consisting of two separate laboratory suites. The facility is AIM's operations, research and development center.

The production of the new Alferon N Injection Active Pharmaceutical Ingredient, or API, is currently on hold. The New Brunswick facility, which we no longer operate, was approved by the FDA under the Biological License Application, or BLA, for Alferon N Injection. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon N Injection API, we will need FDA approval as to the quality and stability of the final product before commercial sales can resume. We may need additional funds to finance the validation process. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon N Injection inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product

will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

In December 2020, we added Pharmaceutics International Inc. (“Pii”) as a “Fill & Finish” provider to enhance our capacity to produce Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our active and in-process fill and finish capacity.

We believe, and are investigating, Ampligen’s potential role in enhancing the activity of influenza vaccines. While certain studies involving rodents, non-human primates (monkeys) and healthy human subjects indicate that Ampligen may enhance the activity of influenza vaccines by conferring increased cross-reactivity or cross-protection, further studies will be required and no assurance can be given that Ampligen will assist in the development of a universal vaccine for influenza or other viruses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This Report also refers to estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Overview

General

AIM ImmunoTech Inc. and its subsidiaries (collectively, “AIM”, “Company”, “we” or “us”) are an immuno-pharma company headquartered in Ocala, Florida, and focused on the research and development of therapeutics to treat multiple types of cancers, viral diseases and immune-deficiency disorders. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids and natural interferon to enhance the natural antiviral defense system of the human body, and to aid the development of therapeutic products for the treatment of certain cancers and chronic diseases.

Our flagship products are Ampligen® (rintatolimod) — a first-in-class drug of large macromolecular RNA (ribonucleic acid) molecules — and Alferon N Injection® (Interferon alfa-n3). Ampligen has not been approved by the FDA or marketed in the United States. Ampligen is approved for commercial sale in the Argentine Republic for the treatment of severe CFS.

Our primary business focus involves Ampligen. Ampligen represents a dsRNA being developed for globally important cancers, viral diseases and disorders of the immune system.

We currently are proceeding primarily in four areas:

- Conducting a randomized, controlled study to evaluate efficacy and safety of Ampligen compared to a control group to treat locally advanced pancreatic cancer patients.
- Exploring and Evaluating Ampligen in other cancers, as a potential therapy that modifies the tumor microenvironment with the goal of increasing anti-tumor responses to check point inhibitors and Dendritic Cell Therapeutic Vaccines.
- Exploring Ampligen’s antiviral activities and potential use as a prophylactic or treatment for existing viruses, new viruses and mutated viruses thereof.
- Evaluating Ampligen as a treatment for myalgic encephalomyelitis/chronic fatigue syndrome (“ME/CFS”) and fatigue and/or Post-COVID conditions of fatigue.

We are prioritizing our activities in an order related to the stage of development, with those clinical activities such as pancreatic cancer, ME/CFS and Post-COVID conditions having priority over antiviral experimentation. We intend that priority clinical work be conducted in FDA- or EMA-authorized trials which could support a potential future NDA. However, our antiviral experimentation is designed to accumulate additional preliminary data supporting our hypothesis that Ampligen is a powerful, broad-spectrum prophylaxis and early-onset therapeutic that may confer enhanced immunity and cross-protection. Accordingly, we will conduct our antiviral programs in those venues most readily available and able to generate valid proof-of-concept data, including foreign venues.

Immuno-Oncology.

We are focused on pancreatic cancer because testing results, to date, primarily conducted in the Netherlands, have been very promising. The Netherlands study generated statistically significant data indicating that Ampligen extended survival well beyond the Standard of Care ("SOC"), when compared to well-matched historical controls. These data support the proposition that Ampligen, when administered to either patients with locally advanced or metastatic pancreatic cancer after systemic chemotherapy showed a statistically significant increase in survival rate. In October 2021, we and our Contract Research Organization, Amarex, submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for a planned Phase 2 study of Ampligen as a therapy for locally advanced or metastatic late-stage pancreatic cancer. In August 2022, we received IRB approval of the trial protocol and so announced the trial's commencement. The study is recruiting patients.

Because of the differences in the scale of necessary trials, our initial primary focus when it comes to pancreatic cancer will be cases that are locally advanced, rather than metastatic. The number of different approaches to treating metastatic pancreatic cancer — approaches which would be determined by treating physicians — would require a much larger, far more expensive trial than would a trial for locally advanced pancreatic cancer. Therefore, we are focusing on patients who have completed FOLFIRINOX and have stable disease. In August 2022, we received Institutional Review Board ("IRB") approval of the trial protocol in locally advanced pancreatic cancer and so announced the trial's commencement. Assuming this trial and subsequent planned clinical trials confirm the existing data, our goal is to then submit an NDA for use of Ampligen in pancreatic cancer patients.

Ampligen has also demonstrated in the clinic the potential for standalone efficacy in a number of other solid tumors. We have also seen success in increasing survival rates and efficacy in the treatment of animal tumors when Ampligen is used in combination with checkpoint blockade therapies. In fact, in March 2022 we announced interim data from an investigator-initiated, Phase 2, single-arm, efficacy/safety trial to evaluate the effectiveness of combining intensive locoregional intraperitoneal (IP) chemoimmunotherapy of cisplatin with IP Ampligen (TLR-3 agonist) and IV infusion of the checkpoint inhibitor pembrolizumab for patients with recurrent platinum-sensitive ovarian cancer. We believe that data from the study, which is being conducted by the University of Pittsburgh Medical Center and funded by a Merck grant, demonstrated that when combining three drugs – Ampligen and pembrolizumab, which are both immune therapies, with cisplatin, a chemotherapy – evidence of increased biomarkers associated with T cell chemotaxis and cytolytic function has been seen. Importantly, increases of these biomarkers in the tumor microenvironment have been correlated with favorable tumor responses. These successes in the field of immuno-oncology have guided our efforts toward the potential use of Ampligen as a combinational therapy for the treatment of a variety of solid tumor types. The first of our patent applications in this space was granted by the Netherlands on March 15, 2021.

Please see "*Immuno-Oncology*" below.

Ampligen as an Antiviral.

We have a research and pre-clinical history that indicates broad-spectrum antiviral capability of Ampligen in animals. We hope to demonstrate that it has the same effect in humans. To do this, among other things, we need a population infected with a virus. That is why we have spent significant resources on COVID-19 (the disease caused by SARS-CoV-2) which is active and still infecting many subjects. While much would need to be done to get Ampligen to market as a broad-spectrum antiviral, we believe that it is important to focus our efforts first and foremost on thoroughly proving the concept, especially while there is still a large COVID-19-infected population. Previously, animal studies were conducted that yielded positive results utilizing Ampligen to treat numerous viruses, such as Western Equine Encephalitis Virus, Ebola, Vaccinia Virus (which is used in the manufacture of smallpox vaccine) and SARS-CoV-1. We have conducted experiments in SARS-CoV-2 showing Ampligen has a powerful impact on viral replication. The prior studies of Ampligen in SARS-CoV-1 animal experimentation may predict similar protective effects against SARS-CoV-2.

The FDA has requested that we provide additional data to assist the agency in evaluating the potential risks and benefits of administering Ampligen to asymptomatic and mild COVID-19 individuals. However, as discussed in more detail below, where the threat to the patient from COVID-19 is high, the FDA has already authorized Ampligen in a clinical trial of patients with COVID-19 who have a pre-existing cancer. We have also elected to explore studies (initially with healthy volunteers) outside the United States and have already conducted a study in the Netherlands to determine the safety profile of the intranasal delivery of Ampligen.

In this regard, CHDR, a foundation located in Leiden in the Netherlands, managed a Phase 1 randomized, double-blind study for us to evaluate the safety, tolerability and biological activity of repeated administration of Ampligen intranasally. A total of 40 healthy subjects received either Ampligen or a placebo in the trial, with the Ampligen given at four escalating dosages across four cohorts, to a maximum level of 1,250 micrograms. The study was completed and the Final Safety Report reported no Serious or Severe Adverse Events at any dosage level.

Today, over two years after COVID-19 first appeared, the world has a number of vaccines and some promising therapeutics. Our quest to prove the antiviral activities of Ampligen continues. If Ampligen has the broad-spectrum antiviral properties that we believe that it has, it could be a very valuable tool in treating variants of existing viral diseases, including COVID-19, or novel ones that arise in the future. Unlike most developing therapeutics which attack the virus, Ampligen works differently. We believe that it activates antiviral immune system pathways that fight not just a particular virus or viral variant, but other similar viruses as well.

In July 2023, we enrolled and dosed the first patient in our Phase 2 study evaluating Ampligen® as a potential therapeutic for people with post-COVID conditions ("AMP-518"). We announced in August 2023 that the study had met the planned enrollment of 80 AMP-518 subjects ages 18 to 60 years who have been randomized 1:1 to receive twice-weekly intravenous infusions of Ampligen or placebo for 12 weeks, with a follow-up phase of two weeks. We expect to complete dosing of the last study subject in Q4 2023. Topline data is expected as early as Q1 2024.

Please see "*Ampligen as a Potential Antiviral*" below.

Ampligen as a treatment for ME/CFS and Post-COVID Conditions

We have long been focused on seeking the FDA's approval for the use of Ampligen to treat myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"). In fact, in February 2013, we received a Complete Response letter ("CRL") from the FDA for our Ampligen NDA for ME/CFS, stating that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses.

While developing a comprehensive response to the FDA and a plan for a confirmatory trial for the FDA NDA, we proceeded independently in Argentina and, in August 2016, we received approval of an NDA from ANMAT for commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. On June 10, 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. The next steps in the commercial launch of Ampligen include ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is ongoing due to ANMAT's internal processes. Once final approval by ANMAT is obtained, GP Pharm will be responsible for distributing Ampligen in Argentina.

The FDA authorized an open-label treatment protocol ("AMP-511") allowing patient access to Ampligen for treatment in a study under which severely debilitated CFS patients have the opportunity to be on Ampligen to treat this very serious and chronic condition. The data collected from the AMP-511 protocol through a consortium group of clinical sites provide safety information regarding the use of Ampligen in patients with CFS. The AMP-511 protocol is ongoing. In October 2020, we received IRB approval for the expansion of the AMP-511 protocol to include patients previously diagnosed with SARS-CoV-2 following clearance of the virus, but who still demonstrate chronic fatigue-like symptoms that we refer to as Post-COVID conditions. As of September 30, 2023, there were 11 patients enrolled in this open-label expanded access treatment protocol (including four patients with Post-COVID Conditions). To date, there have been seven such Post-COVID patients treated in the study. AIM previously reported positive preliminary results based on data from the first four Post-COVID Condition patients enrolled in the study. The data show that, by week 12, compared to baseline, there was what the investigators considered a clinically significant decrease in fatigue-related measures.

We plan on a comprehensive follow through with the FDA regarding the use of Ampligen as a treatment for ME/CFS. We have learned a great deal since the FDA's CRL and plan to adjust our approach to concentrate on specific ME/CFS symptoms. Responses to the CRL and a proposed confirmatory trial are being worked on now by our R&D team and consultants.

Please see "*Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)*" below.

OUR PRODUCTS

Our primary pharmaceutical product platform consists of Ampligen (rintatolimod), a first-in-class drug of large macromolecular double-stranded (ds) RNA (ribonucleic acid) molecules, and our FDA-approved natural alpha-interferon product, Alferon N Injection.

Ampligen®

Ampligen is approved for sale in Argentina (to 2026) for severe CFS and is an experimental drug in the United States currently undergoing clinical development for the treatment of certain cancers and ME/CFS. Over its developmental history, Ampligen has received various designations, including Orphan Drug Product Designation (FDA and EMA), Treatment protocol (e.g., "Expanded Access" or "Compassionate" use authorization) with Cost Recovery Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ" or Agency for Healthcare Research and Quality). Based on the results of published, peer-reviewed pre-clinical studies and clinical trials, we believe that Ampligen may have broad-spectrum antiviral and anti-cancer properties.

We believe that nucleic acid compounds represent a potential new class of pharmaceutical products designed to act at the molecular level for treatment of many human diseases. Ampligen represents the first drug in the class of large (macromolecular) dsRNA molecules to apply for NDA review. There are two forms of nucleic acids: deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA"). DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which comprise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically configured RNA and is a selective Toll-like Receptor 3 ("TLR3") agonist that can be administered intravenously, intranasally and intraperitoneally. Ampligen has been assigned the generic name rintatolimod by the United States Adopted Names Council ("USANC") and has the chemical designation poly(I):poly(C_{12}U).

Expanded Access Program/Early Access Programs/clinical trials of Ampligen that have been conducted or that are ongoing include studies of the potential treatment of patients with pancreatic cancer, renal cell carcinoma, malignant melanoma, non-small cell lung cancer, ovarian cancer, breast cancer, colorectal cancer, prostate cancer, ME/CFS, Hepatitis B, HIV, COVID-19 and Post-COVID conditions.

We have received approval of our NDA from ANMAT for the commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. Shipment of the drug product to Argentina was initiated in 2018 to complete the release testing by ANMAT needed for commercial distribution. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. In June 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. We are currently working with GP Pharm on the commercial launch of Ampligen in Argentina. Commercialization in Argentina will require, among other things, GP Pharm to establish disease awareness, medical education, creation of an appropriate reimbursement level, design of marketing strategies and completion of manufacturing preparations for launch and ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. AIM has supplied GP Pharm with the Ampligen required for testing and ANMAT release. This testing and approval process is ongoing due to ANMAT's internal processes. The ongoing impact of COVID-19 in Argentina is taxing the nation's health care system and is, understandably, the main priority of its regulators. Once final approval by ANMAT is obtained, GP Pharm will begin distributing Ampligen in Argentina. We continue to pursue our Ampligen NDA, for the treatment of CFS with the FDA.

The FDA has authorized an open-label expanded access treatment protocol (AMP-511) allowing patient access to Ampligen in a study under which severely debilitated CFS patients have the opportunity to be on Ampligen to treat this serious and chronic condition. The AMP-511 protocol started in the 1990s and is ongoing. The data collected from the AMP-511 protocol through clinical sites provide safety information regarding the use of Ampligen in patients with CFS. We are establishing an enlarged database of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our future filings for Ampligen and/or the design of future clinical studies that the FDA requested in a CRL. The FDA approved an increased reimbursement level from $200 to $345 per 200 mg vial of Ampligen, due to increased production costs; which was re-authorized in 2021 and again in 2022. At this time, we do not plan on passing this adjustment along to the patients in this program. In October 2020, we received IRB approval for the expansion of the AMP-511 Expanded Access Program clinical trial for ME/CFS to include patients previously diagnosed with SARS-CoV-2 following clearance of the virus, but who still demonstrate chronic fatigue-like symptoms that we refer to as Post-COVID conditions. As of September 30, 2023, there are 11 patients enrolled in this open-label expanded access treatment protocol (including four Post-COVID patients). To date, there have been eight such Post-COVID patients treated. In July 2022, AIM reported positive preliminary results based on data from the first four Post-COVID Condition patients enrolled in the study. The data show that, by week 12, compared to baseline, the investigators observed what they considered a clinically significant decrease in fatigue-related measures.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an Early Access Program ("EAP") in Europe and Turkey related to ME/CFS. Pursuant to the agreement, as amended, myTomorrows also is managing all Early Access Programs and Special Access Programs in Europe, Canada and Turkey to treat pancreatic cancer and ME/CFS patients. The agreement was automatically extended for a period of 12 months on May 20, 2021; has been automatically extended for 12 months on each subsequent May 20; and will continue to be automatically extended for periods of 12 months every May 20 until terminated or the terms of the agreement are met.

In June 2018, Ampligen was cited as outperforming two other TLR3 agonists — poly IC and natural double stranded RNA — in creating an enhanced tumor microenvironment for checkpoint blockade therapy in the journal of *Cancer Research* (http://cancerres.aacrjournals.org/content/early/2018/05/31/0008-5472.CAN-17-3985). In a head-to-head study in explant culture models, Ampligen activated the TLR3 pathway and promoted an accumulation of killer T cells but, unlike the other two TLR3 agonists, it did so without causing regulatory T cell (Treg) attraction. These findings were considered important because they indicate that Ampligen selectively reprograms the tumor microenvironment by inducing the beneficial aspects of tumor inflammation (attracting killer T cells), without amplifying immune-suppressive elements such as regulatory T cells. The study was conducted at the University of Pittsburgh and Roswell Park as a part of the NIH-funded P01 CA132714 and Ovarian Cancer Specialized Program of Research Excellence ("SPORE").

In 2018, we completed production of two commercial-size batches of more than 16,000 vials of Ampligen, following its "Fill & Finish" at Jubilant HollisterStier, the Contract Manufacturing Organization. These lots passed all required testing for regulatory release for human use and are being used for multiple programs, including: the treatment of ME/CFS; the pancreatic cancer EAP in the Netherlands; and will continue to be used for ongoing and future clinical studies in oncology. Additionally, two lots of Ampligen were manufactured in December 2019 and January 2020 at Jubilant HollisterStier and we recently issued a purchase order for a total of $1,432,257 to manufacture additional lots of Ampligen at Jubilant. The current manufactured lots of Ampligen have been fully tested and released for commercial product launch in Argentina and for clinical trials. Additionally, in December 2020, we added Pii as a "Fill & Finish" provider to enhance our capacity to produce Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our active and in-process fill and finish capacity.

Immuno-Oncology

The potential of Ampligen as an immuno-oncology therapeutic has been a major focus of AIM since our current leadership took over in 2016. We have been working with the University of Pittsburgh's chemokine modulation research initiative, which includes the use of Ampligen as a potential adjuvant to modify the tumor microenvironment ("TME") with the goal of increasing anti-tumor responses to check point inhibitors ("CPI"). As part of this collaboration, we have supplied Ampligen to the University. The study, under the leadership of Robert P. Edwards, MD, chair of gynecologic services at Magee-Women's Hospital of the University of Pittsburgh School of Medicine, and Professor of Surgery Pawel Kalinski, M.D., Ph.D., at Roswell Park, Buffalo, N.Y., involved the chemokine modulatory regimen developed by Dr. Kalinski's group and successfully completed the Phase 1 dose escalation in patients with resectable colorectal cancer.

Multiple Ampligen clinical trials are underway or recently completed at major university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint inhibitors. The underway trials include:

- **Pancreatic Cancer Trial** - The Phase 2 AMP-270 clinical trial is a randomized, open-label, controlled, parallel-arm study with the primary objective of comparing the efficacy of Ampligen versus a no treatment control group following FOLFIRINOX for subjects with locally advanced pancreatic adenocarcinoma. Secondary objectives include comparing safety and tolerability. The AMP-270 is expected to enroll approximately 90 subjects in up to 30 centers across the U.S. and Europe. The Buffett Cancer Center at the University of Nebraska Medical Center (UNMC) and Erasmus MC in the Netherlands are expected to be the primary study sites. In March 2022, the FDA granted clearance to proceed with the study. In April 2022, we executed a work order with Amarex to manage the clinical trial. In August 2022, we received IRB approval of the trial protocol and so announced the trial's commencement. The study is recruiting patients. (https://clinicaltrials.gov/ct2/show/NCT05494697).

See "Immuno-Oncology; Additional Progress and Analysis Related to Pancreatic Cancer" for more analysis.

- **Advanced Recurrent Ovarian Cancer**

- Results of the Phase 1 portion of a Phase 1/2 study of intraperitoneal chemo-immunotherapy in advanced recurrent ovarian cancer were published in the American Association for Cancer Research publication, Clinical Cancer Research (Clin Cancer Res January 19, 2022 DOI: 10.1158/1078-0432.CCR-21-3659). The study results represent an important extension of prior studies using human tumor explants that showed Ampligen's potentially important role as a TLR3 agonist acting synergistically with high-dose IFNα and celecoxib to selectively enhance Teff cell-attractants while suppressing Treg-attractants in the tumor microenvironment with a concomitant increase in the Teff/Treg ratio. The importance of boosting the Teff/Treg ratio in the tumor microenvironment is that it is associated with the conversion of 'cold' tumors into 'hot' tumors, which have an increased sensitivity to chemo-immunotherapy and an improved chance of showing tumor regression. The Phase 1 portion was designed to establish intraperitoneal safety. The Phase 2 portion of the study is planned to be conducted in the future. https://clinicaltrials.gov/ct2/show/NCT02432378

- A Phase 2 study of advanced recurrent ovarian cancer using cisplatin, pembrolizumab, plus Ampligen; up to 45 patients to be enrolled; enrollment has commenced, and numerous patients have commenced treatment. We announced interim data from the study demonstrating that evidence of increased biomarkers associated with T cell chemotaxis and cytolytic function was seen when combining Ampligen, pembrolizumab and cisplatin. Increases of these biomarkers in the tumor microenvironment have been correlated with favorable tumor responses. Interim results announced March 2022 detailed an observed clinical response rate of 61% includes two complete and three partial tumor responses, plus three patients with stable disease among the 13 evaluable patients. An important priority will be to confirm these findings through continuing to enroll patients onto this study. https://clinicaltrials.gov/ct2/show/NCT03734692

In March 2021, we were granted a patent by the Netherlands Patent Office with granted patent claims that include, but are not limited to, the use of Ampligen as a combination cancer therapy with checkpoint blockade inhibitors (e.g. pembrolizumab, nivolumab). Interim data from an investigator-initiated, Phase 2, single-arm, efficacy/safety trial demonstrated that evidence of increased biomarkers associated with T cell chemotaxis and cytolytic function was seen when combining Ampligen, pembrolizumab and cisplatin. It is critical to note that increases of these biomarkers in the tumor microenvironment have been correlated with favorable tumor responses. All told, the study has seen an Objective Response Rate (ORR) of 38.5%; a study of pembrolizumab alone in the treatment of advanced recurrent ovarian cancer found ORR of 8.1% and 9.9% across two cohorts. We believe that the positive data makes this patent have heightened potential. Similar patents are pending in other countries.

- **Stage 4 Metastatic Triple Negative Breast Cancer** - Phase 1 study of metastatic triple-negative breast cancer using chemokine modulation therapy, including Ampligen and pembrolizumab. Eight patients were enrolled and 6 patients were evaluable. https://www.clinicaltrials.gov/ct2/show/NCT03599453. The key findings announced April 2022 included:
  - The pre-determined primary endpoint of efficacy was met (increase in CD8 in TME).
  - Uniform increase of immune markers upon treatment was observed: CD8 mRNA (6.1-fold; p-0.034), GZMB mRNA (3.5-fold; p=0.058), ratios of CD8 /FOXP3 and GZMB/FOXP3 (5.7-fold; p=0.036, and 7.6-fold; p=0.024 respectively), thus successfully meeting the pre-determined primary endpoint in the study (increase in CD8 in TME).
  - In addition, an increase in CTL attractants CXCL10 (2.6-fold; p=0.104) and CCL5 (3.3-fold; p=0.019) was observed. In contrast, Treg marker FOXP3 or Treg attractants CCL22 or CXCL12 were not enhanced.
  - Three patients had stable disease lasting 2.4, 2.5 and 3.8 months, as of data cut off September 1, 2021.
  - An additional patient (non-evaluable) had a partial response (breast tumor autoamputation) with massive tumor necrosis in the post-CKM biopsy.
- **Stage 4 Colorectal Cancer Metastatic to the Liver** - Phase 2a study of Ampligen as a component of chemokine modulatory regimen on colorectal cancer metastatic to liver; recruitment has been completed; 19 patients were enrolled and 12 patients were evaluable for the primary endpoint https://clinicaltrials.gov/ct2/show/NCT03403634. The key findings announced April 2022 included:
  - The study's primary endpoint was met, evidenced by increased CD8a expression post-treatment (p=0.046).
  - Saw increase in the CD8a/CD4 (p=0.03), CD8a/FOXP3 (p<0.01) and GZMB/FOXP3 (p<0.01) ratios.
  - The expression of CTL-attracting chemokines CCL5 (p=0.08), CXCL9 (p=0.05), and CXCL10 (p=0.06) were increased, while expression of the Treg/MDSC attractant CXCL12 (p=0.07) was decreased post-treatment.
  - Median OS was 10.5 (90% CI 2.2-15.2) months, and the median PFS was 1.5 (90% CI 1.4, 1.8) months.
  - No tumor responses were seen. The treatment was well tolerated. Of all enrolled patients (N=19), adverse events were noted in 74% of patients, with the most common being fatigue (58%). Grade 3 or higher adverse events were rare (5%).

- **Early-Stage Prostate Cancer** - Phase 2 study investigating the effectiveness and safety of aspirin and Ampligen with or without interferon-alpha 2b (Intron A) compared to no drug treatments in a randomized three-arm study of patients with prostate cancer before undergoing radical prostatectomy. Patient enrollment has been initiated in this study designed for up to 45 patients. The study is temporarily suspended due to the Merck discontinuation of Intron-A production. Roswell Park has had a Type-C meeting with the FDA and is currently performing the necessary experiments to replace Intron-A with a generic alpha-interferon. We expect this trial to resume in the near future. https://clinicaltrials.gov/ct2/show/NCT03899987

- **Early-Stage Triple Negative Breast Cancer** - The objective of this Phase 1 study is to evaluate the safety and tolerability of a combination of Ampligen, celecoxib with or without Intron A, when given along with chemotherapy in patients with early-stage triple negative breast cancer. The now completed (as of September 2022) topline results from the study confirm the positive findings that were previously presented at the 2022 Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting in a poster presentation titled *Safety and efficacy of de-escalated neoadjuvant chemoimmunotherapy of triple negative breast cancer (TNBC) using chemokine-modulating regimen (rintatolimod, IFN-α2b, celecoxib)*. The primary endpoint of the study was safety and tolerability. The results demonstrated that treatment was well-tolerated with mostly grade 1 or 2 treatment-related adverse events (TRAEs) without dose-limiting toxicities (DLTs) or delayed or immune-related toxicities. DLT was defined as grade 3 or higher toxicities within the first 3 weeks. Secondary endpoints included pCR rate where 5/9 (56%) of patients attained pCR and 1 more patient attained ypTmic. Tumor and blood biomarkers were also analyzed in exploratory studies

- https://clinicaltrials.gov/ct2/show/NCT04081389

- **Refractory Melanoma** — Roswell Park Comprehensive Cancer Center ("Roswell Park"), in a clinical trial fully funded by the National Cancer Institute (NCI), has commenced patient enrollment in its Phase 2 study in subjects with primary PD-1/PD-L1 resistant melanoma. The Phase 2 study will evaluate type-1 polarized dendritic cell (αDC1) vaccine in combination with tumor-selective chemokine modulation ("CKM") comprised of Interferon alpha 2b, Ampligen (rintatolimod) and Celecoxib. Up to 24 patients are to be enrolled. The study is temporarily suspended due to the Merck discontinuation of Intron-A production. Roswell Park has had a Type-C meeting with the FDA and is currently performing the necessary experiments to replace Intron-A with a generic alpha-interferon. We expect this trial to resume in the near future. (See: https://www.clinicaltrials.gov/show/NCT04093323).

- **Metastatic or Unresectable Triple Negative Breast Cancer** - This phase 1/2a trial tests the safety, side effects, and best dose of chemokine modulation therapy (CKM) (rintatolimod, celecoxib, and interferon alpha 2b) in combination with pembrolizumab for the treatment of patients with triple negative breast cancer that has spread from where it first started (primary site) to other places in the body (metastatic) or that cannot be removed by surgery (unresectable). https://clinicaltrials.gov/study/NCT05756166

Additional Progress and Analysis Related to Pancreatic Cancer

In January 2017, the EAP established under our agreement with myTomorrows to enable access of Ampligen to ME/CFS patients was extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program. In February 2018, the agreement with myTomorrows was extended to cover Canada to treat pancreatic cancer patients, pending government approval. There have been no physician requests to date that would cause the program to move forward with the approval process.

A total of 42 pancreatic cancer patients initially received treatment with Ampligen immuno-oncology therapy under the EAP program at Erasmus MC in the Netherlands; that initial program has since continued to expand and proceed with additional patients to be treated with Ampligen Supervised by Prof. C.H.J. van Eijck, MD. The team at Erasmus MC in September 2020 reported data which demonstrated a statistically significant positive survival benefit when using Ampligen in patients with locally advanced or metastatic pancreatic cancer after systemic chemotherapy, compared with historical control patients. Additional patients have since been enrolled and, we believe, the data further confirms the original findings. We are working with our Contract Research Organization, Amarex Clinical Research LLC, to seek FDA "fast-track." We have applied for fast-track status; have received denials to date; and are currently working through the FDA process to provide all the materials and information required to achieve fast-track status. The IND authorization to proceed with the Phase 2 pancreatic cancer clinical trial has been received with potential sites in the Netherlands at Erasmus MC under Prof. C.H.J. van Eijck, and also at major cancer research centers in the United States such as The Buffett Cancer Center at the University of Nebraska Medical Center (UNMC).

In January 2023, we entered into an external sponsored collaborative clinical research agreement with Erasmus MC and AstraZeneca. Under the agreement, Erasmus MC is planning to perform an investigator-initiated clinical study, entitled "Combining anti-PD-L1 immune checkpoint inhibitor durvalumab with TLR-3 agonist rintatolimod in patients with metastatic pancreatic ductal adenocarcinoma for therapy effect. DURIPANC Study," in which it will use study drugs provided by both AstraZeneca and us. In June 2023 we received the required approvals from the Central Committee on Research Involving Human Subjects, which is the Competent Authority for the review of clinical trials in the Netherlands, and the Medical Ethics Review Committee Erasmus MC, which is the governing ethics board.

Additionally:

- In December 2020, the FDA granted Ampligen Orphan Drug Designation status for the treatment of pancreatic cancer. The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the treatment, prevention or diagnosis of a rare disease or condition, which is one that affects less than 200,000 persons in the United States or meets cost recovery provisions of the act. The status helps incentivize the treatment of therapies to treat unmet medical needs by providing a company with seven years of exclusivity rights once a drug reaches market.
- In February 2021, our subsidiary, NV Hemispherx Biopharma Europe, received formal notification from the European Commission ("EC") granting Orphan Medicinal Product Designation for Ampligen as a treatment for pancreatic cancer. Orphan products, once commercially approved in the European Union ("EU"), receive benefits including up to ten years of protection from market competition from similar medicines with similar active component and indication for use that are not shown to be clinically superior.

In June 2021, Ampligen was featured in a publication containing state-of-the-art methodologies in the peer-reviewed medical journal Cancers as a potential treatment option for cancer patients who are infected with SARS-CoV-2. The study's authors stated that Ampligen has the potential to reduce the severity of the deadly respiratory disease COVID-19. According to laboratory data presented in the publication, "Rintatolimod [Ampligen] activated the innate and the adaptive immune systems by activating a cascade of actions in human pancreatic cancer cells", including:

- Stimulation of interferon regulatory factors and activation of the interferon signaling pathway,
- Production of immunomodulatory activity and
- Induction of the expression of MHC class I and II histocompatibility

The full journal article is titled: "Rintatolimod Induces Antiviral Activities in Human Pancreatic Cancer Cells: Opening for an Anti-COVID-19 Opportunity in Cancer Patients?" *Cancers* is a peer-reviewed, open access journal of oncology published semimonthly online by MDPI. The study's authors include Prof. C.H.J. van Eijck, MD, PhD, the lead investigator at Erasmus Medical Center in the Netherlands.

In October 2021, we and Amarex submitted an IND application with the FDA for a planned Phase 2 study of Ampligen as a therapy for locally advanced or metastatic late-stage pancreatic cancer. In December 2021, the FDA responded with a Clinical Hold on the proposed study. We submitted our response to the FDA in February 2022. In March 2022, we received notification from the FDA that the Clinical Hold was released and cleared, meaning that we are now able to proceed with the study specifically to treat locally advanced pancreatic cancer patients. In August 2022, we received IRB approval of the trial protocol and so announced the trial's commencement. The study is recruiting patients.

Positive data was published in March 2022 in a manuscript titled, "Rintatolimod (Ampligen®) enhances numbers of peripheral B cells and is associated with longer survival in patients with locally advanced and metastasized pancreatic cancer pre-treated with FOLFIRINOX: a single-center named patient program," in *Cancers Special Issue: Combination and Innovative Therapies for Pancreatic Cancer*. In the single-center, named-patient program, patients with locally advanced pancreatic cancer (LAPC) or metastatic disease were treated with Ampligen for 6 weeks, at 2 doses per week with 400 mg per infusion. The study found that Ampligen improved the median survival of these patients. The study's primary endpoints were the Systemic Immune-Inflammation Index (SIII), the Neutrophils to Lymphocyte Ratio (NLR), and absolute counts of 18 different populations of circulating immune cells as measured by flow cytometry. Secondary endpoints were progression-free survival (PFS) and overall survival (OS). The median overall survival in the Ampligen group was 19 months, compared to a historical control group and subgroup (7.5 and 12.5, respectively) that did not receive Ampligen.

Also in March 2022, we announced that study data evaluating the direct effects of Ampligen on human pancreatic ductal adenocarcinoma (PDAC) cells was accepted for presentation at the 15th Annual International Hepato-Pancreato-Biliary Association World Congress in New York, NY. For the study, three PDAC cell lines (CFPAC-1, MIAPaCa-2, and PANC-1) were treated with various concentrations of Ampligen and their corresponding vehicle control. The proliferation and migration effects were examined using in-vitro assays and the molecular effect was examined by targeted gene expression profiling. Additionally human PDAC samples were used to validate the expression of toll-like receptor 3 (TLR3) by immunohistochemistry. Results from the study demonstrated Ampligen decreased the proliferation and migration ability of CFPAC-1 cells. In addition, it decreased the proliferation of MIAPaCa-2 cells and the migration of PANC-1 cells. However, it did not have a dual effect in MIAPaCa-2 and PANC-1 cells. Interestingly, TLR3 was highly expressed in CFPAC-1 cells, low expressed in MIAPaCa-2 and not expressed in PANC-1. Gene expression analysis revealed the upregulation of interferon-related genes, chemokines, interleukins and cell cycle regulatory genes. The heterogeneity of TLR3 expression was confirmed in human PDAC samples. Based on these results, treating pancreatic cancer with Ampligen may have a direct anti-tumor effect in pancreatic cancer cells expressing TLR-3.

On April 4, 2023, AIM executed an Unrestricted Grant Agreement with Erasmus University Medical Center pursuant to which Erasmus MC will use its best efforts to diligently carry out immune monitoring in pancreatic cancer patients. On April 5, 2023, the Company entered into a Consulting Agreement with Casper H.J. van Eijck, MD, PhD, pursuant to which, among other things, Dr. van Eijck will assist the Company in recruiting and assisting sites outside of the Netherlands to participate in clinical trials evaluating Ampligen for the treatment of pancreatic cancer.

On June 27, 2023, we announced the publication of pre-clinical data that suggests Ampligen has the potential to act directly on tumor cells to reduce tumor cell growth in pancreatic cancer patients with sufficient tumor levels of TLR-3, suggesting a potential biomarker to identify patients who may respond to Ampligen. The anti-tumor analysis was published in the peer-reviewed journal *American Journal of Cancer Research* in the paper "Rintatolimod: A potential treatment in patients with pancreatic cancer expressing Toll-like receptor 3."

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), also known as Chronic Fatigue Immune Dysfunction Syndrome ("CFIDS") and Chronic Fatigue Syndrome (CFS), is a serious and debilitating chronic illness and a major public health problem. ME/CFS is recognized by both the government and private sector as a significant unmet medical need, including the U.S. National Institutes of Health ("NIH"), FDA and the CDC. The CDC states on its website at https://www.cdc.gov/me-cfs/ that "*Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a serious, long-term illness that affects many body systems. People with ME/CFS are often not able to do their usual activities. At times, ME/CFS may confine them to bed. People with ME/CFS have severe fatigue and sleep problems. ME/CFS may get worse after people with the illness try to do as much as they want or need to do. This symptom is called post-exertional malaise (PEM). Other symptoms can include problems with thinking and concentrating, pain, and dizziness.*"

Many severe ME/CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. ME/CFS is characterized by incapacitating fatigue with profound exhaustion and extremely poor stamina, sleep difficulties and problems with concentration and short-term memory. It is also accompanied by flu-like symptoms, pain in the joints and muscles, tender lymph nodes, sore throat and new headaches. A distinctive characteristic of the illness is a worsening of symptoms following physical or mental exertion, which do not subside with rest.

The high number of younger people being hospitalized for COVID-19 suggests considerable numbers of people in the prime of their lives may have a COVID-induced ME/CFS-like illness in their future. According to a 2016 journal article, the estimated annual cost of lost productivity related to ME/CFS was $9-37 billion in the United States, and for direct medical costs it was $9-14 billion.

In June of 2020, we filed a provisional patent application for, among other discoveries, the use of Ampligen as a potential early-onset therapy for the treatment of COVID-19 induced chronic fatigue.

Many survivors of the first SARS-CoV-1 epidemic in 2003 continued to report chronic fatigue, difficulty sleeping and shortness of breath months after recovering from the acute illness. "After one year, 17% of patients had not returned to work and 9% more had not returned to their pre-SARS work levels," according to Simmaron Research. Now there is increasing evidence that patients with COVID-19 can develop a similar, ME/CFS-like illness. These patients are commonly referred to as "Long Haulers."

In October 2020, we received IRB approval for the expansion of the AMP-511 Expanded Access Program clinical trial for ME/CFS to include patients previously diagnosed with SARS-CoV-2 following clearance of the virus, but who still demonstrate chronic fatigue-like symptoms. For more information on our AMP-511 Expanded Access Program, please see "*OUR PRODUCTS: Ampligen*" above.

In November 2020, we announced the publication of statistically significant data detailing how Ampligen could have a considerable positive impact on people living with ME/CFS when administered in the early stages of the disease. The data were published in *PLOS ONE*, a peer-reviewed open access scientific journal published by the Public Library of Science. AIM researchers found that the TLR3 agonist Ampligen substantially improved physical performance in a subset of ME/CFS patients.

As noted above in *Overview; General; Ampligen as a treatment for ME/CFS and Post-COVID Conditions*, we have long been focused on seeking the FDA's approval for the use of Ampligen to treat ME/CFS. In fact, in February 2013, we received a CRL from the FDA for our Ampligen NDA for ME/CFS, stating that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses.

While developing a comprehensive response to the FDA and a plan for a confirmatory trial for the FDA NDA, we proceeded independently in Argentina and, in August 2016, we received approval of an NDA from ANMAT for commercial sale of Ampligen in the Argentine Republic for the treatment of severe CFS. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. On June 10, 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. The next steps in the commercial launch of Ampligen include ANMAT conducting a final inspection of the product and release tests before granting final approval to begin commercial sales. This testing and approval process is currently delayed due to the COVID-19 pandemic and ANMAT's internal processes. The ongoing impact of COVID-19 in Argentina is taxing the nation's health care system and is, understandably, the main priority of its regulators. Once final approval by ANMAT is obtained, GP Pharm will begin distributing Ampligen in Argentina.

We plan on a comprehensive follow through with the FDA regarding the use of Ampligen as a treatment for ME/CFS. We have learned a great deal since the FDA's CRL and plan to adjust our approach to concentrate on specific ME/CFS symptoms. Responses to the CRL and a proposed confirmatory trial are being worked on now by our R&D team and consultants.

Ampligen as a Potential Antiviral

Following the SARS-CoV-1 outbreak in 2002-03, Ampligen exhibited excellent antiviral properties and protective survival effect in NIH-contracted studies of SARS-CoV-1-infected mice, which is very similar to SARS-CoV-2, the novel virus that causes COVID-19.

- The Barnard 2006 study (https://journals.sagepub.com/doi/abs/10.1177/095632020601700505) found that Ampligen reduced virus lung levels to below detectable limits.
- The Day 2009 study (https://www.sciencedirect.com/science/article/pii/S0042682209005832) found that, instead of 100% mortality, there was 100% protective survival using Ampligen.

We compared key transcription regulatory sequences of SARS-CoV-1 to SARS-CoV-2 and found significant similarities, suggesting highly probable extension of the antiviral effects of Ampligen in the earlier NIH-contracted SARS experiments to COVID-19. The SARS-CoV-2 virus – which causes COVID-19 – shares important genomic and pathogenic similarities with SARS-CoV-1 (hence its name). Since Ampligen has shown antiviral activity against more distantly related coronaviruses, there was a reasonable probability that the antiviral effects of Ampligen against SARS-CoV-1 will likely extend to SARS-CoV-2, and as discussed below, recently, Ampligen has demonstrated ex vivo antiviral activity against SARS-CoV-2. We believe that this creates a compelling case for clinical trials to evaluate Ampligen as a potential tool in the fight against COVID-19.

Since the late 2019 outbreak of SARS-CoV-2, we have been actively engaged in determining whether Ampligen could be an effective treatment for this virus or could be part of a vaccine. We believe that Ampligen has the potential to be both an early-onset treatment for and prophylaxis against SARS-CoV-2. We believe that prior studies of Ampligen in SARS-CoV-1 animal experimentation may predict similar protective effects against the new virus.

In February 2020, we filed three provisional patent applications related to Ampligen in our efforts toward joining the global health community in the fight against the deadly coronavirus (See: https://aimimmuno.com/press-release/aim-immunotech-files-provisional-patent-application-for-the-use-of-ampligenr-as-a-potential-therapy-for-covid-19-induced-chronic-fatigue/). Our three provisional patent applications include: 1) Ampligen as a therapy for the coronavirus; 2) Ampligen as part of a proposed intranasal universal coronavirus vaccine that combines Ampligen with inactivated coronavirus, conveying immunity and cross-protection and; 3) a high-volume manufacturing process for Ampligen. Under the Patent Cooperation Treaty of 1970, which provides international protections for patents, these three provisional patent applications were converted into two international patent applications based on the date of their filings.

In August 2020, we contracted Amarex to act as our Clinical Research Organization and provide regulatory support with regard to a possible clinical trial testing Ampligen's potential as a COVID-19 prophylaxis via intranasal delivery.

Beginning in April 2020, we entered into confidentiality and non-disclosure agreements with numerous companies for the potential outsourcing of the production of polymer, enzyme, placebo as well as Ampligen, and one Contract Research Organization, Amarex, which will provide regulatory and monitoring support related to a clinical trial testing Ampligen's intranasal safety and potential as a COVID-19 prophylaxis via intranasal delivery.

In May 2020, the FDA authorized an IND for Roswell Park to conduct a Phase 1/2a study of a regimen of Ampligen and interferon alpha in cancer patients with COVID-19 infections. This clinical trial, sponsored by Roswell Park in collaboration with us, will test the safety of this combination regimen in patients with cancer and COVID-19, and the extent to which this therapy will promote clearance of the SARS-CoV-2 virus from the upper airway. Several subjects have been treated. It is planned that the phase 1/2a study will enroll up to 44 patients in two stages. Phase 1 will see 12-24 patients receiving both Ampligen and interferon alpha-2b at escalating doses. Once that initial phase is complete, further study participants will be randomized to two arms: one receiving the two-drug combination and a control group who will not receive Ampligen or interferon alpha but will receive best available care. We are a financial sponsor of the study and will provide Ampligen at no charge for this study. In November 2020, the first patient in the study had been enrolled and treated. This study was amended to add 20 patients, with 10 randomized to receive a single dose of Ampligen and 10 patients to receive current best therapies. (See clinicaltrials.gov/NCT04379518). Due to a shortage of qualifying subjects with COVID-19 and cancer as a result of the positive impact of vaccinations and treatments for COVID-19, Roswell is seeking approval to expand the qualifying subject criteria to include other diseases lethal to immuno-compromised cancer patients, such as influenza. Accordingly, the study is temporarily suspended while seeking said approvals.

We also entered into a specialized services agreement with Utah State University and have supplied Ampligen to support the University's Institute for Viral Research in its research into SARS-CoV-2. The Utah State results show that Ampligen was able to decrease SARS-CoV-2 infectious viral yields by 90% at clinically achievable intranasal Ampligen dosage levels.

In October 2020, we received IRB approval for the expansion of the AMP-511 Expanded Access Program clinical trial for ME/CFS to include patients previously diagnosed with SARS-CoV-2, but who still demonstrate chronic fatigue-like symptoms. Patients in the trial are treated with our flagship pipeline drug Ampligen. In January 2021, we commenced with the treatment of the first previously diagnosed COVID-19 patient with long-COVID symptoms (i.e., Long Hauler) also known as Post-COVID Conditions in the AMP-511 study. Enrollment of post-COVID patients continues in the study.

In January 2021, we entered into a Sponsor Agreement with CHDR to manage a Phase 1 randomized, double-blind study to evaluate the safety and activity of repeated intranasal administration of Ampligen. AIM funded and sponsored the study. This study was designed to assess the safety, tolerability and biological activity of repeated administration of Ampligen intranasally. A total of 40 healthy subjects received either Ampligen or a placebo in the trial, with the Ampligen given at four escalating dosages across four cohorts, to a maximum level of 1,250 micrograms. The study was completed and the Final Safety Report reported no Serious or Severe Adverse Events at any dosage level. We believe that the trial is a critical step in our ongoing efforts to develop Ampligen as a potential prophylaxis or treatment for COVID-19 and other respiratory viral diseases. Amarex provided us with monitoring support during the trial.

Additionally, we filed two COVID-19-related provisional patent applications in the third quarter of 2021. In August, we filed an application for Ampligen as both an intranasal and an intravenous therapy for what we describe as Post-COVID conditions. The people suffering from Post-COVID conditions, including some young adults, can be afflicted with severe difficulties in concentrating; serious memory problems; and the inability to live an active lifestyle, to work and even to perform everyday tasks. Early data has demonstrated that patients with symptoms of Post-COVID conditions being treated with Ampligen in the ongoing AMP-511 Expanded Access Program have reported improvements in fatigue symptoms. Similarly, in ME/CFS, data supports the claim that Ampligen improves fatigue symptoms. Then in September 2022, we filed a patent application for Ampligen as a potential early-onset intranasal therapy designed to enhance and expand infection-induced immunity, epitope spreading, cross-reactivity and cross-protection in patients exposed to a wide range of RNA respiratory viruses, such as influenza, Rhinoviruses and SARS-CoV-2.

In addition to securing these two provisional patent applications, we also moved forward with proposed studies in these areas and with Pre-Investigational New Drug Applications in September 2021. One pre-IND was for a Phase 2, two-arm, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Ampligen in patients experiencing Post-COVID conditions (originally referred to as Post-COVID Cognitive Dysfunction (PCCD) and has been revised to Post-COVID conditions).

In July 2023, we enrolled and dosed the first patient in our Phase 2 study evaluating Ampligen® as a potential therapeutic for people with post-COVID conditions ("AMP-518"). We announced in August 2023 that the study had met the planned enrollment of 80 AMP-518 subjects ages 18 to 60 years who have been randomized 1:1 to receive twice-weekly intravenous infusions of Ampligen or placebo for 12 weeks, with a follow-up phase of two weeks. We expects to complete dosing of the last study subject in Q4 2023. Topline data is expected as early as Q1 2024.

On May 9, 2023, we were granted a U.S. Patent for a method for preventing or reducing antigenic drift or viral reassortment in a host animal comprising determining if a host animal has been exposed to or infected by an avian influenza virus and administering to the exposed host animal alpha-interferon.

Other Diseases

In Europe, the EMA has approved the Orphan Medicinal Products Designation for Ampligen as a potential treatment of Ebola virus disease and for Alferon N Injection as a potential treatment of MERS.

We concluded our series of collaborations designed to determine the potential effectiveness of Ampligen and Alferon N Injection as potential preventive and/or therapeutic treatments for Ebola-related disorders. Although we believe that the threat of both MERS and Ebola globally may reemerge in the future, it appears that the spread of these disorders has diminished.

In April 2021, we entered into an MTA with the University of Cagliari Dipartimento di Scienze della Vita e dell'Ambiente ("UNICA"), an educational institution, under the laws of Italy, located in Monserrato (Cagliari), Italy. The MTA relates to the research and development of the effects of Ampligen and its ability to induce interferon production in several cell lines, and also on the ability of the Ebola virus protein VP35 to bind to viral dsRNA and impede interferon's upregulation and activity, and on Ampligen's ability to reverse VP35 inhibition of interferon production in biological systems. The data analysis was published in the peer-reviewed journal *Antiviral Research*, in a manuscript titled "Ebola virus disease: In vivo protection provided by the PAMP restricted TLR3 agonist rintatolimod and its mechanism of action." We believe that the analysis supports a dual mechanism of action when Ampligen is used as a prophylactic therapy against Ebola Virus Disease.

In May 2021, we filed a U.S. Provisional Patent Application for Ampligen as a potential therapeutic to possibly slow, halt, or reverse the progression of Alzheimer's disease.

In November 2022, we received notice that the FDA had granted Orphan Drug Designation to Ampligen for the treatment of Ebola virus disease.

Alferon N Injection®

Alferon N Injection is the registered trademark for our injectable formulation of natural alpha interferon. Alferon N Injection is the only natural-source, multi-species alpha interferon currently approved for sale in the United States and Argentina for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Alferon N Injection is also approved in Argentina for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferons. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). According to the CDC, HPV is the most common sexually transmitted infection, with approximately 79 million Americans — most in their late teens and early 20s — infected with HPV. In fact, the CDC states that "HPV is so common that nearly all sexually active men and women get the virus at some point in their lives." Although they do not usually result in death, genital warts commonly recur, causing significant morbidity and entail substantial health care costs.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the United States. Our natural alpha interferon is produced from human white blood cells. The potential advantages of natural alpha interferon over recombinant (i.e., synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon products each contain only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (i.e., partially covered with sugar molecules). Such glycosylation is not present on the currently U.S.-marketed recombinant alpha interferons. We believe that the absence of glycosylation may be in part responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

Alferon N Injection [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no neutralizing antibodies observed against Alferon N Injection to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year of treatment, probably due to neutralizing antibody formation (See "Manufacturing" and "Marketing/Distribution" sections below for more details on the manufacture and marketing/distribution of Alferon N Injection). The production of new Alferon N Injection Active Pharmaceutical Ingredient, or API, is currently on hold. We do not know when, if ever, our products will be generally available for commercial sale for any indication. Additionally, on May 9, 2023, we were granted a U.S. Patent for a method for preventing or reducing antigenic drift or viral reassortment in a host animal comprising determining if a host animal has been exposed to or infected by an avian influenza virus and administering to the exposed host animal alpha-interferon.

MANUFACTURING

ANMAT in Argentina approved Ampligen for commercial distribution for the treatment of CFS in 2016. Shipment of the drug product to Argentina was initiated in 2018 to complete the release testing by ANMAT needed for commercial distribution. In September 2019, we received clearance from the FDA to ship Ampligen to Argentina for the commercial launch and subsequent sales. In June 2020, we received import clearance from ANMAT to import the first shipment of commercial grade vials of Ampligen into Argentina. We are currently working with GP Pharm on the commercial launch of Ampligen in Argentina (See "Our Products; Ampligen" above).

Following our approval in Argentina, in 2017 we engaged Jubilant HollisterStier ("Jubilant") to be our authorized CMO for Ampligen. Two lots of Ampligen consisting of more than 16,000 units were manufactured and released in 2018; these lots have been designated for human use in the United States in the cost recovery CFS program and for expanded oncology clinical trials. The production of additional polymer (Ampligen intermediates) took place in 2019 at our New Brunswick facility. Additionally, Jubilant manufactured two more lots of Ampligen in December 2019 and January 2020. The current manufactured lots of Ampligen have been fully tested and released for commercial product launch in Argentina and for clinical trials. In addition, we have supplied GP Pharm with the Ampligen required for testing and ANMAT release. Once final approval by ANMAT is obtained, we anticipate that GP Pharm will begin distributing Ampligen in Argentina.

In December 2020, we added Pii as a "Fill & Finish" provider to enhance our capacity to produce Ampligen. This addition amplifies our manufacturing capability by providing redundancy and cost savings. The contracts augment our existing fill and finish capacity. We are prepared to initiate the production of additional Ampligen when and if needed.

In June 2022 we entered into a lease agreement with the New Jersey Economic Development Authority for a 5,210 square-foot, state-of-the-art R&D facility at the New Jersey Bioscience Center (NJBC), primarily consisting of two separate laboratory suites. The lease commenced on July 1, 2022, and runs through August 31, 2027, but can be extended for an additional five-year period. The facility is AIM's operations, research and development center.

Our business plan calls for the utilization of one or more CMOs to produce Ampligen API. While we believe we have sufficient Ampligen API to meet our current needs, we are also continually exploring new efficiencies so as to maximize our ability to fulfill future obligations. In this regard, on December 5, 2022, we entered into a Master Service Agreement and a Quality Agreement with Sterling Pharma Solutions ("Sterling") for the manufacture of our Poly I and Poly C12U polynucleotides and transfer of associated test methods at Sterling's Dudley, UK location to produce the polymer precursors to manufacture the drug Ampligen. We are utilizing Sterling's expertise to refine our approach to polymer production. While we believe we have sufficient Ampligen API to meet current needs, we are also continually exploring new efficiencies in order to maximize its ability to fulfill future obligations. In March 2023, we submitted a work order for a total of $1,432,257 to manufacture additional lots of Ampligen at Jubilant.

Our second product, Alferon N Injection, is approved by the FDA for commercial sales in the United States for the treatment of genital warts. It is also approved by ANMAT in Argentina for commercial sales for the treatment of genital warts and in patients who are refractory to treatment with recombinant interferons. Commercial sales of Alferon N Injection in the United States will not resume until new batches of commercial filled and finished product are produced and released by the FDA. We will need the FDA's approval to release commercial product once we have identified our new manufacturing approach and submitted satisfactory stability and quality release data. Currently, we are not manufacturing Alferon N Injection and there is no definitive timetable to resume production.

LICENSING/COLLABORATIONS/JOINT VENTURES

To enable potential availability of Ampligen to patients on a worldwide basis, we have embarked on a strategy to license the product and/or to collaborate and/or create a joint venture with companies that have the demonstrated capabilities and commitment to successfully gain approval and commercialize Ampligen in their respective global territories of the world. Ideal partners would have the following characteristics: well-established global and regional experience and coverage; robust commercial

infrastructure; a strong track record of successful development and registration of in-licensed products; and a therapeutic area fit (e.g., ME/CFS, immuno-oncology).

MARKETING/DISTRIBUTION

In May 2016, we entered into a five-year exclusive Renewed Sales, Marketing, Distribution and Supply Agreement (the "Agreement") with GP Pharm. Under this Agreement, GP Pharm was responsible for gaining regulatory approval in Argentina for Ampligen to treat severe CFS in Argentina and for commercializing Ampligen for this indication in Argentina. We granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. We also granted GP Pharm an option to market Alferon N Injection in Argentina and other Latin America countries (See "Our Products; Ampligen" above). The GP Pharm contract was extended in May 2021, and will now end on May 24, 2024. In August 2021, ANMAT granted a five-year extension to a previous approval to sell and distribute Ampligen to treat severe CFS in Argentina. This extends the approval until 2026.

In May 2016, we entered into a five-year agreement (the "Impatients Agreement") with Impatients, N.V. ("myTomorrows"), a Netherlands-based company, for the commencement and management of an EAP in Europe and Turkey (the "Territory") related to ME/CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in the Territory, is performing EAP activities. These activities will be directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization (regulatory approval) through named-patient use, compassionate use, expanded access and hospital exemption, (b) patient and physician outreach related to a patient-physician platform, (c) the securing of Early Access Approvals (exemptions and/or waivers required by regulatory authorities for medical treatments prior to Marketing Authorization) for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance (drug safety) activities and/or (f) the collection of data such as patient-reported outcomes, doctor-reported experiences and registry data. We are supporting these efforts and supplying Ampligen to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. Pursuant to the Impatients Agreement, the royalty would be a percentage of Net Sales (as defined in the Impatients Agreement) of Ampligen sold in the Territory where Marketing Authorization was obtained. The formula to determine the percentage of Net Sales will be based on the number of patients that are entered into the EAP. We believe that disclosure of the exact maximum royalty rate and royalty termination date could cause competitive harm. However, to assist the public in gauging these terms, the actual maximum royalty rate is somewhere between 2% and 10% and the royalty termination date is somewhere between five and fifteen years from the First Commercial Sale of a product within a specific country. The parties established a Joint Steering Committee comprised of representatives of both parties to oversee the EAP. No assurance can be given that activities under the EAP will result in Marketing Authorization or the sale of substantial amounts of Ampligen in the Territory. The agreement was automatically extended for a period of 12 months on May 20, 2021; has been automatically extended for 12 months on each subsequent May 20; and will continue to be automatically extended for periods of 12 months every May 20 until terminated or the terms of the agreement are met.

In January 2017, ANMAT granted a five-year extension to a previous approval to sell and distribute Alferon N Injection (under the brand name "Naturaferon") in Argentina. This extended the approval until 2022. A request to extend the approval beyond 2022 has been filed and is still under review. In February 2013, we received ANMAT approval for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon, with Naturaferon in Argentina.

In January 2017, the EAP through our agreement with myTomorrows designed to enable access of Ampligen to ME/CFS patients was extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in the Territory and will manage all EAP activities relating to the pancreatic cancer extension of the program.

In August 2017, we extended our agreement with Asembia LLC, formerly Armada Healthcare, LLC, to undertake the marketing, education and sales of Alferon N Injection throughout the United States. This agreement has expired. We were in discussions with Asembia about the possibility of continuing the relationship, while also exploring the possibility of working with other, similar companies. However, we still do not foresee an immediate need for this service and continue to push this search further out in our expected timeline.

In February 2018, we signed an amendment to the EAP with myTomorrows. This amendment extended the Territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to the EAP with myTomorrows, pursuant to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of ME/CFS.

In December 2020, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to 16 pancreatic cancer patients. In November 2021, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to an additional 5 pancreatic cancer patients. In March 2022, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to an additional 10 pancreatic cancer patients. In November 2022, we entered into a signed Letter of Agreement with myTomorrows for the delivery of Ampligen for the treatment of up to an additional 10 pancreatic cancer patients.

401(k) Plan

We have a defined contribution plan, entitled the AIM ImmunoTech Employees 401(k) Plan and Trust Agreement (the "401(k) Plan"). Our full-time employees are eligible to participate in the 401(k) Plan following 61 days of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants' contributions to the 401(k) Plan may be matched by us at a rate determined annually by the Board.

Each participant immediately vests in his or her deferred salary contributions as well as our safe harbor contributions. A 6% safe harbor matching contribution by us was reinstated effective January 1, 2021. For the nine months ending September 30, 2023, we made $116,881 in contributions, and for the year ending December 31, 2022 $122,000 was contributed.

New Accounting Pronouncements

See **"**Note 10: Recent Accounting Pronouncements".

Critical Accounting Estimates

There have been no material changes in our critical accounting estimates from those disclosed in Part II; Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations; Critical Accounting Policies" contained in our Annual Report on Form 10-K for the year ended December 31, 2022.

RESULTS OF OPERATIONS

Three months ended September 30, 2023 versus three months ended September 30, 2022

Net Loss

Net losses were $7,816,000 and $6,385,000 for the three months ended September 30, 2023, and 2022, respectively, representing an increase in loss of $1,431,000 or 22%. This increase in loss was primarily due to the following:

- an increase in research and development expenses of $1,361,000
- an increase in production costs of $30,000;
- a decrease in gain from sale of income tax operating losses of $10,000
- an increase in general and administrative expenses of $269,000; offset by,
- an increase in interest and other income of $122,000,
- a decrease in loss on investments, net of $55,000,
- an increase in the gain on sale of fixed assets of $39,000.

The net loss per share was $(0.16) and $(0.13) for the three months ended September 30, 2023, and 2022, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2023, was 48,635,165 compared with 48,079,210 as of September 30, 2022.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $46,000 and $21,000 for the three months ended September 30, 2023 and 2022, respectively. The change was due primarily to the increase in drug utilization for the AMP-511 study for the two sites that are open and treating patients.

Production Costs

Production costs were approximately $30,000 and $0 for the three months ended September 30, 2023, and 2022, respectively, representing an increase of $30,000 in production costs in the current period. The increase was due to the cost incurred for production of Ampligen that will occur in the last quarter of 2023.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2023, were $2,734,000, compared with $1,372,000 for the same period a year ago, reflecting an increase of $1,362,000. The primary reason for the increase in research and development costs was largely due to increases in manufacturing costs of $1,502,000, clinical trial costs of $1,404,000 and engineering and maintenance costs of $40,000, net of decreases in regulatory cost of $1,402,000 and quality control costs of $189,000.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2023, and 2022, were approximately $5,439,000 and $5,170,000, respectively, reflecting an increase of $269,000. The increase in G&A expenses during the current period was primarily due to an increase in professional fees of $570,000 and salaries of $113,000 net with a decrease in stock compensation of $225,000, insurance of $87,000, taxes and licenses of $65,000 and moving expenses of $40,000.

Loss on Investments

Loss on Investments for the three months ended September 30, 2023, and 2022 were $310,000 and $365,000, respectively, reflecting a decrease in loss of approximately $55,000. This decrease in loss on investments for the three months ended September 30, 2023, was due to the change in fair value of equity investments.

Interest and Other Income

Interest and other income for the three months ended September 30, 2023, and 2022 was $294,000 and $172,000, respectively. This represents a net increase of approximately $122,000.

Gain from sale of income tax operating losses

The quarterly income tax benefit for the three months ended September 30, 2023 resulted in a gain of $318,000 compared to a gain of $328,000 for the three months ended September 30, 2022 due primarily to a deferred tax asset recorded in 2023 for the New Jersey NOL.

Nine months ended September 30, 2023 versus nine months ended September 30, 2022

Net Loss

Net losses were $16,386,000 and $15,056,000 for the nine months ended September 30, 2023, and 2022, respectively, representing an increase in loss of $1,330,000 or 9%. This increase in loss was primarily due to the following:

- an increase in research and development expenses of $2,856,000,
- an increase in general and administrative expenses of $712,000,
- an increase in production costs of $30,000; offset by,
- a decrease in loss on investments of $1,568,000
- an increase in interest and other income of $515,000,
- an increase in gain from sale of Income tax operating of $151,000.

Net loss per share was $(0.34) and $(0.31) for the nine months ended September 30, 2023, and 2022, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2023, was 48,483,802 as compared with 48,036,559 as of September 30, 2022.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $137,000 and $85,000 for the nine months ended September 30, 2023 and 2022, respectively. The change of $52,000 is primarily related to the increase in drug utilization for the AMP-511 study for the two sites that are open and treating patients.

Production Costs

Production costs were approximately $30,000 and $0 for the nine months ended September 30, 2023, and 2022, respectively, representing an increase of $30,000 in production costs in the current period. The increase was due to the cost incurred for production of Ampligen that will occur in the last quarter of 2023.

Research and Development Costs

Overall R&D costs for the nine months ended September 30, 2023, were $7,739,000 compared with $4,883,000 for the same period a year ago, reflecting an increase of $2,856,000. The primary cause of the increase in research and development costs was attributable to increases in manufacturing costs of $1,872,000 and clinical trial expense of $1,212,000, net of a decrease in quality control costs of $215,000.

General and Administrative Expenses

G&A expenses for the nine months ended September 30, 2023, and 2022, were approximately $10,280,000 and $9,569,000, respectively, reflecting an increase of $711,000. The increase in G&A expenses during the current period was primarily due to an increase in professional fees of $1,336,000 net with a decrease in stock compensation of $610,000.

Loss on Investments

Loss on Investments for the nine months ended September 30, 2023, and 2022 were $201,000 and $1,769,000, respectively, reflecting a decrease in loss of approximately $1,568,000. This decrease in loss on investments for the nine months ended September 30, 2023, was due to the change in fair value of equity investments.

Interest and Other Income

Interest and other income for the nine months ended September 30, 2023, and 2022 was $811,000 and $296,000, respectively. This represents a net increase of approximately $515,000.

Redeemable Warrants

The quarterly revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability. There was no change for the nine months ended September 30, 2023, compared with a gain of $35,000 for the nine months ended September 30, 2022 (see “Financial Statements: Note 11: Fair Value” for the various factors considered in the valuation of redeemable warrants).

Gain from sale of income tax operating losses

The quarterly income tax benefit for the nine months ended September 30, 2023, was $900,000 compared with $749,000 for the nine months ended September 30, 2022, due primarily to a change in the deferred tax asset recorded for the New Jersey NOL.

Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2023, was $11,509,000 compared with $10,039,000 used in operating activities during first nine months of 2022, representing a change of $1,470,000. The primary reasons for this change in cash used in operations in 2023 was related to non-cash charges which primarily consisted of a decrease of $610,000 in stock compensation, $1,567,000 of loss on investments and $35,000 of gain from sale of income tax operating losses. The main changes in working capital were an increase in accounts payable and prepaid expenses a decrease in accrued expenses.

Cash used in investing activities for the nine months ended September 30, 2023, was $618,000 compared with cash provided by investing activities for the same period in 2022 of $7,625,000, representing a change of $8,243,000. The primary reason for the change for the periods ended September 30, 2023, and September 30, 2022, is the sale of marketable investments of $924,000 and $9,082,000, respectively, net with the purchase of marketable investments for the same time period of $1,155,000 and $1,661,000, respectively.

Cash provided by financing activities for the nine months ended September 30, 2023, was approximately $338,000 compared with $80,000 provided during the same period in 2022, an increase of 258,000. The primary reason for this increase was our receipt of $338,000 in net proceeds from the sale of shares in the first nine months of 2023 compared with the receipt of $80,000 in net proceeds from the sale of shares for the same period in 2022.

As of September 30, 2023, we held $22,431,000 in cash, cash equivalents and marketable investments, which included $7,167,000 of marketable investments, representing a decrease of approximately $11,759,000 from cash and investments held at December 31, 2022.

The decrease was primarily due to cash used by operations ($11,500,000). Operating cash usage stemmed primarily from an operating loss of $16,400,000 during the nine months ended September 30, 2023, which was offset by $1,600,000 received from the sale of our tax net operating loss in New Jersey, and $2,400,000 of increased accounts payable utilization.

For the nine months ended September 30, 2023, our largest expenditures were professional fees (31.7%), the largest portion of which related to the ongoing shareholder dispute, clinical trials, and research (30.7%) and salaries and wages (18.6%).

Clinical trials and research expenses vary based on multiple factors, but primarily relate to the number of participants enrolled in the studies. The costs related to these studies have increased in 2023 when compared with 2022, as the number of participants has risen. This is positive news for the advancement of our developing product but requires substantial cash outlays to operate the studies.

As discussed in the general overview section, we are proceeding in four primary areas. Proceeding simultaneously in these areas should allow our product to reach the market more quickly than if they were each conducted consecutively but requires additional capital resources to do so. A portion of the increase related to the $1,400,000 purchase of product needed to supply our ongoing trials. This purchase provided sufficient product to sustain the studies for an extended period and is not expected to be normally recurring.

Salaries and wages have not increased materially compared with the prior year.

We are committed to a focused business plan oriented toward finding senior co-development partners with the capital and expertise needed to commercialize the many potential therapeutic aspects of our experimental drugs and our FDA approved drug Alferon N Injection.

The development of our products requires the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. We believe, based on our current financial condition, that we have adequate funds to meet our anticipated operational cash needs and fund current clinical trials over approximately the next sixteen months from September 30, 2023. In this regard, in April 2023, we entered into an Equity Distribution Agreement (the “EDA”), with Maxim Group LLC (“Maxim”), pursuant to which we may sell from time to time, shares of our common stock having an aggregate offering price of up to $8.5 million through Maxim, as agent. For the nine months ended September 30, 2023, we sold 327,055 shares under the EDA for total gross proceeds of $209,000, which includes a 3.0% fee to Maxim of $6,271. At present we do not generate any material revenues from operations, and we do not anticipate doing so in the near future. We may need to obtain additional funding in the future for new studies and/or if current studies do not yield positive results, require unanticipated changes and/or additional studies. If we are unable to commercialize and sell Ampligen and/or recommence material sales of Alferon N Injection, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required. There can be no assurances that, if needed, we will be able to raise adequate funds from the EDA or otherwise or enter into licensing, partnering or other arrangements to advance our business goals. We may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. See Part I, Item 1A - “Risk Factors; *We may require additional financing which may not be available*” in our Annual Report on Form 10-K for the year ended December 31, 2022.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

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

ITEM 4: Controls and Procedures

Our Chief Executive Officer (“CEO”) and the Chief Financial Officer (“CFO”) performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our CEO and CFO concluded that the controls and procedures were effective as of September 30, 2023, to ensure that material information was accumulated and communicated to our management, including our CEO and CFO, is appropriate to allow timely decisions regarding required disclosure.

During the three months ended September 30, 2023, we made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part II – OTHER INFORMATION

ITEM 1: Legal Proceedings

Please see Part I, Item 3. *Legal Proceedings* in our Annual Report on Form 10-K for the year ended December 31, 2022 and Note 14: *Subsequent Events* in the financial statements included herein.

ITEM 1A: Risk Factors

Please carefully consider the factors discussed below and the factors identified in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 31, 2023 and our subsequent filings with the SEC, that could materially affect our business and financial condition and could cause results to differ materially from those expressed in forward-looking statements contained in this Report or other reports filed with the SEC. The risks described below and in the above reports are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and operating results. Please also see "Special Note Regarding Forward-Looking Statements" above.

ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

Not Applicable.

ITEM 6: Exhibits

(i) Exhibits - See exhibit index below.

Exhibit No.	Description
3.1	Certificate of Increase of Series A Junior Participating Preferred Stock (incorporated by reference to exhibit 3.1 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended March 31, 2023).
3.1(ii)	Amended and Restated By-Laws of Registrant (incorporated by reference to exhibit 3.7(ii) to the Company's Annual report on Form 10-K (No. 001-27072) for year ended December 31, 2022).
4.1	Third Amended and Restated Rights Agreement, dated May 12, 2023 between AIM ImmunoTech Inc. (formerly, Hemispherx Biopharma, Inc.) and American Stock Transfer & Trust Company, LLC. (incorporated by reference to exhibit 4.6 to Amendment No. 3 to the Company's Registration Statement on Form 8-A12B (No. 001-27072) filed May 15, 2023).
10.1	June 27, 2022 First Amendment to Agreement of Sale and Purchase with Acellories, Inc. (incorporated by reference to exhibit 10.86 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended June 30, 2022).
10.2	August 2, 2022 Second Amendment to Agreement of Sale and Purchase with Acellories, Inc. (incorporated by reference to exhibit 10.87 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended June 30, 2022).
10.3	October 5, 2022 Lease extension for Riverton office (incorporated by reference 10.4 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.4	October 11, 2022 Material Transfer and Research Agreement with University of Pittsburgh (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference 10.5 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.5	October 21, 2022 Material Transfer and Research Agreement with University of Pittsburgh (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference 10.6 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.6	October 21, 2022 Fourth Amendment to Agreement of Sale and Purchase with Acellories, Inc (incorporated by reference 10.7 to the Company's Quarterly report on Form 10-Q (No. 001-27072) for the period ended September 30, 2022 filed November 14, 2022).
10.7	December 5, 2022 Master Service Agreement between Sterling Pharma Solutions Limited and AIM ImmunoTech Inc. (incorporated by reference 10.93 to the Company's Annual report on Form 10-K (No. 001-27072) for year ended December 31, 2022).
10.8	January 13, 2023 Study Support Agreement with Erasmus University Medical Center Rotterdam (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference 10.94 to the Company's Annual report on Form 10-K (No. 001-27072) for year ended December 31, 2022).
10.9	January 13, 2023 Co-ordination Agreement with Erasmus University Medical Center Rotterdam and AstraZeneca BV (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference 10.95 to the Company's Annual report on Form 10-K (No. 001-27072) for year ended December 31, 2022).

10.10	March 1, 2023 Extension Agreement with Foresite Advisors LLC (incorporated by reference 10.96 to the Company's Annual report on Form 10-K (No. 001-27072) for year ended December 31, 2022).
10.11	April 4, 2023 Unrestricted Grant Agreement with Erasmus University Medical Center (incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K (No. 001-27072) filed April 7, 2023).
10.12	April 5, 2023 Independent Contractor Service Agreement with Casper H.J van Eijck (incorporated by reference to exhibit 10.2 to the Company's Current Report on Form 8-K (No. 001-27072) filed April 7, 2023).
10.13	April 19, 2023 Equity Distribution Agreement with Maxim Group, LLC (incorporated by reference to exhibit 10.2 to the Company's Current Report on Form 8-K (No. 001-27072) filed April 19, 2023).
10.14	Material Transfer and Research Agreement, dated as of May 22, 2023, with Japanese National Institute of Infectious Disease (portions of this agreement have been redacted in compliance with Regulation S-K Item 601(b)(10)) (incorporated by reference to 10.1 to the Company's Current Report on Form 8-K (No. 001-27072) filed May 30, 2023).
10.15	September 20, 2023 Amended and Restated Material Transfer and Research Agreement with Roswell Park Cancer Institute Corporation d/b/a Roswell Park Comprehensive Cancer Center (incorporated by reference to Exhibit 10.1 to the Company's Current Report of Form 8-K (No. 001-27072) filed September 29, 2023).
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer. *
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer. *
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer. *
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer. *
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Schema
101.CAL	Inline XBRL Taxonomy Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Definition Linkbase
101.LAB	Inline XBRL Taxonomy Label Linkbase
101.PRE	Inline XBRL Taxonomy Presentation Linkbase
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

* Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

AIM IMMUNOTECH INC.

/s/ Thomas K. Equels

Thomas K. Equels, Esq.
Chief Executive Officer & President

/s/ Robert Dickey IV

Robert Dickey IV
Chief Financial Officer

Date: November 14, 2023

EXHIBIT 31.1

CERTIFICATIONS PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Thomas K. Equels, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AIM ImmunoTech Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

    d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

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

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

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

Date: November 14, 2023 May 15, 2024

/s/ Thomas K. Equels

Thomas K. Equels, Esq.
Chief Executive Officer & President

EXHIBIT 31.2

CERTIFICATIONS PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Robert Dickey IV, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AIM ImmunoTech Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

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

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

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

Date: November 14, 2023 May 15, 2024

/s/ Robert Dickey IV

Robert Dickey IV
Chief Financial Officer

EXHIBIT 32.1

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of AIM ImmunoTech Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2023 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas K. Equels, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 14, 2023 May 15, 2024

/s/ Thomas K. Equels

Thomas K. Equels, Esq.
Chief Executive Officer & President

EXHIBIT 32.2

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of AIM ImmunoTech Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2023 March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Dickey IV, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 14, 2023 May 15, 2024

/s/ Robert Dickey IV

Robert Dickey IV
Chief Financial Officer

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