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

FORM 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934**

For the month of November 2019

Commission File Number 001-38716

GAMIDA CELL LTD.
(Translation of registrant's name into English)

**5 Nahum Heftsadie Street
Givaat Shaul, Jerusalem 91340 Israel
(Address of principal executive offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

INCORPORATION BY REFERENCE

Exhibits 99.1 and 99.2 to this Report on Form 6-K shall be deemed to be incorporated by reference into the Registration Statement or [Form S-8](#) (Registration Number 333-228301) of Gamida Cell Ltd. (the “Company”) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit 99.3 to this Report on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act.

RISK FACTORS

The risk factors set forth under the caption “Risk Factors” in the Company’s annual report on Form 20-F filed on February 25, 2019 shall be deemed to be incorporated by reference herein and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Additional risks and uncertainties not currently known to the Company, or that the Company currently deems to be immaterial, also may affect its business, financial condition and/or future operating results.

PFIC STATUS

If we are a passive foreign investment company, or PFIC, we expect to provide investors, by annually posting a “PFIC Annual Information Statement” on our website, with the information required to allow investors to make a qualified electing fund, or QEF, election for United States federal income tax purposes.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

November 13, 2019

GAMIDA CELL LTD.

By: /s/ Shai Lankry
Shai Lankry
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Unaudited Interim Consolidated Statements of Financial Position as of September 30, 2019 and September 30, 2018, and Unaudited Interim Consolidated Statements of Comprehensive Loss, Statements of Changes in Shareholders' Equity and Statements of Cash Flows for the three months ended September 30, 2019 and September 30, 2018
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Press Release dated November 13, 2019
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Interim Consolidated Statements of Financial Position, (ii) Interim Consolidated Statements of Comprehensive Loss, (iii) Interim Consolidated Statements of Changes in Shareholders Equity, (iv) Interim Consolidated Statements of Cash Flows, and (v) the Notes to Interim Consolidated Financial Statements

GAMIDA CELL LTD. AND ITS SUBSIDIARY
INTERIM CONSOLIDATED FINANCIAL STATEMENTS

AS OF SEPTEMBER 30, 2019

U.S. DOLLARS IN THOUSANDS

UNAUDITED

INDEX

	<u>Page</u>
<u>Interim Consolidated Statements of Financial Position</u>	2 - 3
<u>Interim Consolidated Statements of Comprehensive Loss</u>	4
<u>Interim Consolidated Statements of Changes in Equity</u>	5 - 7
<u>Interim Consolidated Statements of Cash Flows</u>	8 - 9
<u>Notes to Interim Consolidated Financial Statements</u>	10 - 17

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands

	<u>September 30,</u>		<u>December 31,</u>
	<u>2019</u>	<u>2018</u>	<u>2018</u>
	<u>Unaudited</u>		<u>Audited</u>
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 39,573	\$ 14,109	\$ 40,272
Available-for-sale financial assets	28,544	9,570	20,417
Prepaid expenses and other current assets	1,134	1,018	1,502
Total current assets	69,251	24,697	62,191
NON-CURRENT ASSETS:			
Property and equipment, net	4,209	1,743	2,311
Right-of-use assets	5,568	-	-
Other assets	651	354	662
Deferred issuance cost	-	1,718	-
Total non-current assets	10,428	3,815	2,973
Total assets	\$ 79,679	\$ 28,512	\$ 65,164

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands (except share and per share data)

	<u>September 30,</u>		<u>December 31,</u>
	<u>2019</u>	<u>2018</u>	<u>2018</u>
	<u>Unaudited</u>		<u>Audited</u>
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	\$ 2,105	\$ 3,060	\$ 1,985
Employees and payroll accruals	3,096	2,128	2,888
Current maturities of lease liabilities	1,926	-	-
Accrued expenses and other payables	1,979	2,111	1,832
Total current liabilities	9,106	7,299	6,705
NON-CURRENT LIABILITIES:			
Liabilities presented at fair value	5,434	15,400	24,049
Employee benefit liabilities, net	280	194	183
Lease liability	4,342	-	-
Liability to Israel Innovation Authority (IIA)	11,594	10,474	9,540
Total non-current liabilities	21,650	26,068	33,772
SHAREHOLDERS' EQUITY:			
Share capital -			
Ordinary shares of NIS 0.01 par value - Authorized: 100,000,000, 23,277,000 and 100,000,000 shares at September 30, 2019 and 2018 and December 31, 2018, respectively; Issued and outstanding: 33,667,326, 699,590 and 24,930,736 shares at September 30, 2019 and 2018 and December 31, 2018, respectively	92	2	67
Preferred shares of NIS 0.01 par value - Authorized: 0, 16,723,000 and 0 shares at September 30, 2019 and 2018 and December 31, 2018, respectively; Issued and outstanding: 0, 14,154,743 and 0 shares at September 30, 2019 and 2018 and December 31, 2018, respectively	-	38	-
Share premium	237,843	141,816	193,953
Capital reserve due to actuarial gains	(160)	(79)	(77)
Available-for-sale reserve	2	(47)	(43)
Accumulated deficit	(188,854)	(146,585)	(169,213)
Total shareholders' equity (deficit)	48,923	(4,855)	24,687
Total liabilities and shareholders' equity	\$ 79,679	\$ 28,512	\$ 65,164

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

U.S. dollars in thousands (except share and per share data)

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
Operating expenses:					
Research and development, net	\$ 21,682	\$ 17,169	\$ 7,363	\$ 5,132	\$ 22,045
General and administrative	12,195	7,008	4,621	2,438	11,599
Operating loss	33,877	24,177	11,984	7,570	33,644
Finance expenses	2,499	6,560	895	2,356	20,259
Finance income	(16,665)	(434)	(2,613)	(104)	(1,042)
Loss before taxes on income	19,711	30,303	10,266	9,822	52,861
Taxes on income (benefit)	(70)	-	(170)	-	70
Net loss	19,641	30,303	10,096	9,822	52,931
Other comprehensive loss:					
Items that will be reclassified subsequently to profit or loss:					
Actuarial net loss of defined benefit plans	83	-	-	-	(2)
Changes in the fair value of available for sale financial assets	(45)	13	(3)	(122)	9
Total comprehensive loss	\$ 19,679	\$ 30,316	\$ 10,093	\$ 9,700	\$ 52,938
Basic net loss per share	\$ 0.70	\$ 43.92	\$ 0.30	\$ 14.23	\$ 10.53
Diluted net loss per share	\$ 1.24	\$ 43.92	\$ 0.30	\$ 14.23	\$ 10.53

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

U.S. dollars in thousands (except share and per share data)

	Ordinary shares		Preferred shares		Share premium	Available -for-sale reserve	Capital reserve due to actuarial losses	Accumulated deficit	Total equity
	Number	Amount	Number	Amount					
Balance as of January 1, 2019 (audited)	24,930,736	\$ 67	-	\$ -	\$ 193,953	(43)	(77)	(169,213)	\$ 24,687
Net loss	-	-	-	-	-	-	-	(19,641)	(19,641)
Other comprehensive loss	-	-	-	-	-	45	(83)	-	(38)
Total comprehensive loss	-	-	-	-	-	45	(83)	(19,641)	(19,679)
Issuance of ordinary shares in a secondary offering, net of issuance expenses in an amount of \$694	8,050,000	\$ 23	-	-	37,117	-	-	-	37,140
Exercise of options	477,278	1	-	-	119	-	-	-	120
Exercise of warrants	209,312	1	-	-	2,923	-	-	-	2,924
Share-based compensation	-	-	-	-	3,731	-	-	-	3,731
Balance as of September 30, 2019 (unaudited)	33,667,326	\$ 92	-	\$ -	\$ 237,843	2	(160)	(188,854)	\$ 48,923

	Ordinary shares		Preferred shares		Share premium	Available -for-sale reserve	Capital reserve due to actuarial losses	Accumulated deficit	Total equity
	Number	Amount	Number	Amount					
Balance as of January 1, 2018 (audited)	689,898	\$ 2	14,154,743	\$ 38	\$ 139,311	(34)	(79)	(116,282)	\$ 22,956
Net loss	-	-	-	-	-	-	-	(30,303)	(30,303)
Other comprehensive loss	-	-	-	-	-	(13)	-	-	(13)
Total comprehensive loss	-	-	-	-	-	(13)	-	(30,303)	(30,316)
Exercise of options	9,692	*)	-	-	2	-	-	-	2
Share-based compensation	-	-	-	-	2,503	-	-	-	2,503
Balance as of September 30, 2018 (unaudited)	699,590	\$ 2	14,154,743	\$ 38	\$ 141,816	(47)	(79)	(146,585)	\$ (4,855)

*) Represents less than \$1.

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

U.S. dollars in thousands (except share and per share data)

	Ordinary shares		Preferred shares		Share premium	Available -for- sale reserve	Capital reserve due to actuarial losses	Accumulated deficit	Total equity	
	Number	Amount	Number	Amount						
Balance as of July 1, 2019 (unaudited)	25,606,423	\$ -	69	\$ -	-	199,402	\$ (1)	(160)	\$ (178,758)	20,552
Net income	-	-	-	-	-	-	-	(10,096)	-	(10,096)
Other comprehensive income	-	-	-	-	-	-	3	-	-	3
Total comprehensive income	-	-	-	-	-	-	3	-	(10,096)	(10,093)
Issuance of ordinary shares in a secondary offering, net of issuance expenses in an amount of \$694	8,050,000	23	-	-	37,117	-	-	-	-	37,140
Exercise of options	10,903	-	-	-	3	-	-	-	-	3
Share-based compensation	-	-	-	-	1,321	-	-	-	-	1,321
Balance as of September 30, 2019 (unaudited)	<u>33,667,326</u>	<u>92</u>	<u>-</u>	<u>-</u>	<u>237,843</u>	<u>2</u>	<u>(160)</u>	<u>(188,854)</u>	<u>48,923</u>	

	Ordinary shares		Preferred shares		Share premium	Available - for-sale reserve	Capital reserve due to actuarial losses	Accumulated deficit	Total equity
	Number	Amount	Number	Amount					
Balance as of July 1, 2018 (unaudited)	689,898	\$ 2	14,154,743	\$ 38	140,934	(169)	(79)	(136,763)	\$ 3,963
Net loss	-	-	-	-	-	-	-	(9,822)	(9,822)
Other comprehensive loss	-	-	-	-	-	122	-	-	122
Total comprehensive loss	-	-	-	-	-	122	-	(9,822)	(9,700)
Exercise options	9,692	*)	-	-	2	-	-	-	2
Share-based compensation	-	-	-	-	880	-	-	-	880
Balance as of September 30, 2018 (unaudited)	<u>699,590</u>	<u>2</u>	<u>14,154,743</u>	<u>38</u>	<u>141,816</u>	<u>(47)</u>	<u>(79)</u>	<u>(146,585)</u>	<u>(4,855)</u>

*) Represents less than \$1.

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

U.S. dollars in thousands (except share and per share data)

	Ordinary shares		Preferred shares		Share premium	Available - for-sale reserve	Capital reserve due to actuarial losses	Accumulated deficit	Total equity
	Number	Amount	Number	Amount					
Balance as of January 1, 2018 (audited)	689,898	\$ 2	14,154,743	\$ 38	\$ 139,311	\$ (34)	\$ (79)	\$ (116,282)	\$ 22,956
Net loss	-	-	-	-	-	-	-	(52,931)	(52,931)
Other comprehensive loss	-	-	-	-	-	(9)	2	-	(7)
Total comprehensive loss	-	-	-	-	-	(9)	2	(52,931)	(52,938)
Issuance of additional preferred shares following Anti-dilution Protection	-	-	3,134,546	8	(8)	-	-	-	-
Exercise of options	9,692	-	-	-	2	-	-	-	2
Conversion of preferred shares	17,289,289	46	(17,289,289)	(46)	-	-	-	-	-
Issuance of ordinary shares in initial public offering, net of issuance expenses in an amount of \$694	6,648,368	18	-	-	47,223	-	-	-	47,241
Exercise of warrants	293,489	1	-	-	3,850	-	-	-	3,851
Share-based compensation	-	-	-	-	3,575	-	-	-	3,575
Balance as of December 31, 2018 (audited)	24,930,736	\$ 67	-	\$ -	\$ 193,953	\$ (43)	\$ (77)	\$ (169,213)	\$ 24,687

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
Cash flows from operating activities:					
Net loss	\$ (19,641)	\$ (30,303)	\$ (10,096)	\$ (9,822)	\$ (52,931)
Adjustments to reconcile net loss to net cash used in operating activities:					
Adjustments to the profit or loss items:					
Depreciation of property, plant and equipment and right-of-use assets	1,792	146	547	49	269
Financial (income) expenses, net	(768)	(161)	(199)	214	(858)
Cost of share-based compensation	3,731	2,503	1,321	880	3,575
Change in employee benefit liabilities, net	14	(6)	6	(23)	(15)
Amortization of premium on available-for-sale financial assets	150	191	49	200	272
Revaluation of financial derivatives	(15,691)	5,100	(2,220)	1,700	17,600
Revaluation of liability to IIA	1,852	3,167	653	567	2,037
	<u>(8,920)</u>	<u>10,940</u>	<u>157</u>	<u>3,587</u>	<u>22,880</u>
Changes in asset and liability items:					
Decrease (increase) in prepaid expenses and other current assets and other assets	113	(1,266)	(4)	(1,637)	942
Increase (decrease) in trade payables	120	670	(124)	1,902	(405)
Increase (decrease) in accrued expenses and other payables and employee and payroll accrual	680	1,071	518	(8)	2,296
	<u>913</u>	<u>475</u>	<u>390</u>	<u>257</u>	<u>2,833</u>
Cash received during the period for:					
Interest received	1,132	570	302	179	792
Interest paid	(92)	-	(41)	-	-
	<u>1,040</u>	<u>570</u>	<u>261</u>	<u>179</u>	<u>792</u>
Net cash used in operating activities	<u>(26,608)</u>	<u>(18,318)</u>	<u>(9,288)</u>	<u>(5,799)</u>	<u>(26,426)</u>
Cash flows from investing activities:					
Purchase of property and equipment	(2,139)	(949)	(1,261)	(246)	(1,645)
Purchase of available-for-sale financial assets	(32,021)	-	(32,021)	-	(10,905)
Proceed from sale of available-for-sale financial assets	-	4,984	-	-	4,949
Proceed from maturity of available-for-sale financial assets	23,789	-	8,049	-	-
Proceeds from bank deposits	-	5,000	-	-	5,000
Investment in restricted bank deposits	-	(150)	-	(150)	(150)
Net cash provided by (used in) investing activities	<u>(10,371)</u>	<u>8,885</u>	<u>(25,233)</u>	<u>(396)</u>	<u>(2,751)</u>

The accompanying notes are an integral part of the interim consolidated financial statements.

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				
<u>Cash flows from financing activities:</u>					
Proceeds from secondary offering, net	37,235	-	37,343	-	-
Receipt of grants from the IIA	202	2,953	35	1,300	612
Proceeds from issuance of shares, initial public offering (payment of issuance expenses), net	(238)	-	-	-	47,479
Payment of lease liabilities	(1,144)	-	(380)	-	-
Exercise of options	120	-	3	-	2
Increase in deferred issuance cost	-	(736)	-	-	-
Net cash provided by financing activities	36,175	2,217	37,001	1,300	48,093
Exchange differences on balances of cash and cash equivalents	105	-	15	-	31
Increase (decrease) in cash and cash equivalents	(699)	(7,216)	2,495	(4,895)	18,947
Cash and cash equivalents at beginning of period	40,272	21,325	37,078	19,004	21,325
Cash and cash equivalents at end of period	<u>\$ 39,573</u>	<u>\$ 14,109</u>	<u>\$ 39,573</u>	<u>\$ 14,109</u>	<u>\$ 40,272</u>

Supplemental disclosure of non-cash financing activities:Significant non-cash transactions:

IIA liability for grants to be received	<u>\$ -</u>	<u>\$ 418</u>	<u>\$ -</u>	<u>\$ 154</u>	<u>\$ -</u>
Exercise of warrants liabilities to equity	<u>\$ 2,924</u>	<u>\$ 2</u>	<u>\$ -</u>	<u>\$ 2</u>	<u>\$ 3,851</u>
Increase in other assets on credit	<u>\$ (95)</u>	<u>\$ 982</u>	<u>\$ (95)</u>	<u>\$ 191</u>	<u>\$ (238)</u>

The accompanying notes are an integral part of the interim consolidated financial statements.

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 1:- GENERAL

- a. Gamida Cell Ltd. (the “Company”), founded in 1998, is an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases.
- b. The Company has created a novel NAM-based cell expansion platform that is designed to enhance the number and functionality of allogeneic donor cells. This proprietary therapeutic platform may enable the development of therapies with the potential to improve treatment outcomes beyond what is possible with current donor-derived therapies.

The lead product candidate, omidubice1 (formally known as NiCord[®]), is an advanced cell therapy in Phase 3 development as a potential life-saving treatment option for patients in need of a bone marrow transplant (BMT). Omidubice1 is currently being evaluated in an international, randomized, multi-center Phase 3 clinical study designed to compare its safety and efficacy to standard umbilical cord blood for allogeneic BMT in approximately 120 patients with no available matched donor. BMT with a graft derived from bone marrow or peripheral blood cells of a matched donor is currently the standard of care treatment for many of these patients, but there is a significant unmet need for patients who cannot find a fully matched donor.

Omidubice1 was granted a Breakthrough Therapy designation from the FDA and an orphan drug designation in the U.S. and in Europe.

In addition to hematologic malignancies, the Company is pursuing the development of omidubice1 for the treatment of bone marrow failure disorders. Omidubice1 is currently being evaluated in a Phase 1/2 clinical trial sponsored by the National Institutes of Health in patients with severe aplastic anemia, a rare, life-threatening hematological disorder. In February 2019, data from this study were reported at the 2019 Transplantation & Cellular Therapy Meetings of the American Society for Blood and Marrow Transplantation and Center for International Blood and Marrow Transplant Research (2019 TCT Annual Meeting). In the initial cohort of three patients, all successfully underwent a BMT consisting of omidubice1 plus a haploidentical stem cell graft. The rapid cord engraftment, sustained hematopoiesis and accelerated immune recovery observed in these patients enabled the initiation of a second cohort of patients to be treated with omidubice1 as a stand-alone graft.

Beyond omidubice1, the Company is developing GDA-201 (formally known as NAM-NK), an investigational natural killer, or NK, cell-based cancer immunotherapy to be used in combination with standard-of-care therapeutic antibodies. NK cells have potent anti-tumor properties and have the advantage over other oncology cell therapies of not requiring genetic matching, potentially enabling NK cells to serve as a universal donor-based therapy when combined with certain antibodies. GDA-201 is currently in an investigator-sponsored Phase 1 study for the treatment of relapsed or refractory non-Hodgkin lymphoma (NHL) and multiple myeloma (MM). Data from the first 14 patients in the study were reported at the 2019 TCT Annual Meeting and demonstrated that GDA-201 was generally well tolerated and clinically active, with three complete responses observed in patients with NHL and one complete response in a patient with MM.

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 1:- GENERAL (Cont.)

- c. The Company is devoting substantially all of its efforts toward research and development activities. In the course of such activities, the Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated deficit as of September 30, 2019 is \$188,854 and negative cash flows from operating activities during the nine month period ended September 30, 2019 is \$26,608. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The interim consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern. The Company requires additional financing in order to continue to fund its current operations and pay existing and future liabilities.
- d. On July 1, 2019, the Company closed a follow-on offering ("offering") of its ordinary shares on the Nasdaq, which resulted in the sale of 7,000,000 ordinary shares at a public offering price of \$5 per share, before underwriting discounts. The underwriters had a 30-day option to purchase up to 1,050,000 additional shares at a public offering price of \$5.00 per share, which they exercised in full. The exercise of the underwriters' option closed on July 8, 2019. The Company received net proceeds from the offering of \$37,140 (net of issuance costs and underwriting discounts of \$3,110).
- e. Definitions:

In these financial statements:

The Company - Gamida Cell Ltd. and its subsidiary

Subsidiary - Gamida Cell Inc., incorporated in 2000 and intended to focus on sales and marketing upon product approval.

Related parties - As defined in IAS 24

Dollar - U.S. dollar

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

- a. The accompanying unaudited interim consolidated financial statements for the nine and three months periods ended September 30, 2019 and 2018 have been prepared in accordance with IAS 34 “Interim Financial Reporting” for interim financial information.

The interim consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Company’s annual consolidated financial statements as of December 31, 2018 and their accompanying disclosures.

The interim consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, but are not necessarily indicative of the results of operations to be anticipated for the full year ending December 31, 2019.

- b. The accounting policies adopted in the preparation of the interim consolidated financial statements are consistent with those followed in the preparation of the company’s annual consolidated financial statements for the year ended December 31, 2018, except for the adoption of new standards effective as of January 1, 2019. The Company has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

- c. IFRS 16 - Leases:

The Company applies, for the first time, IFRS 16 Leases . As required by IAS 34, the nature and effect of these changes are disclosed below.

The Company adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application. The Company elected to use the transition practical expedient allowing the standard to be applied only to contracts that were previously identified as leases and applying IAS 17 and IFRIC 4 at the date of initial application. The Company also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option (“short-term leases”), and lease contracts for which the underlying asset is of low value (“low-value assets”).

The Company has a number of lease contracts, mainly leases of an office building and a production plant. Before the adoption of IFRS 16, the Company classified each of its leases (as lessee) at the inception date as an operating lease. The leased property was not capitalized and the lease payments were recognized as rent expense in profit or loss on a straight-line basis over the lease term. Any prepaid rent and accrued rent were recognized under prepaid expenses and other current assets and accrued expenses and other payables, respectively.

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Upon adoption of IFRS 16, the Company applied a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The standard provides specific transition requirements and practical expedients, which has been applied by the Company.

The Company recognized right-of-use assets and lease liabilities for those leases previously classified as operating leases, except for short-term leases and leases of low-value assets. The right-of-use assets for most leases were recognized based on the carrying amount as if the standard had always been applied, apart from the use of incremental borrowing rate at the date of initial application. In some leases, the right-of-use assets were recognized based on the amount equal to the lease liabilities, adjusted for any related prepaid and accrued lease payments previously recognized. Lease liabilities were recognized based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application.

Based on the foregoing, as of January 1, 2019:

- Right-of-use assets of \$6,973 were recognized and presented separately in the statement of financial position.
- Additional lease liabilities of \$6,900 were recognized and presented separately in the statement of financial position.
- Prepaid expenses and other current assets of \$256 and accrued expenses and other payables of \$183 related to previous operating leases were derecognized.

The carrying amounts of the Company's right-of-use assets and lease liabilities and the movements during the period are set out below:

	Right-of-use assets				Lease liabilities
	Offices and labs	Vehicles	Production plant	Total	
As of January 1, 2019 (audited)	\$ 2,104	\$ 158	\$ 4,711	\$ 6,973	\$ 6,900
Depreciation expenses	(879)	(102)	(570)	(1,551)	-
Interest expenses	-	-	-	-	459
Re-measurement	-	-	14	14	14
Additions	-	132	-	132	132
Payments	-	-	-	-	(1,237)
As of September 30, 2019 (unaudited)	<u>\$ 1,225</u>	<u>\$ 188</u>	<u>\$ 4,155</u>	<u>\$ 5,568</u>	<u>\$ 6,268</u>

The lease liabilities as of January 1, 2019 reconciled to the operating lease commitments as of December 31, 2018 are as follows:

Operating lease commitments as of December 31, 2018	\$ 7,441
Weighted average incremental borrowing rate as of January 1, 2019 (%)	1.45-4.01
Discounted operating lease commitments of January 1, 2019	6,900
Lease liabilities as of January 1, 2019	<u>\$ 6,900</u>

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Set out below are the new accounting policies of the Company upon adoption of IFRS 16, which have been applied from the date of initial application:

1. Right-of-use assets:

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Company is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment.

2. Lease liabilities:

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating a lease, if the lease term reflects the Company exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period on which the event or condition that triggers the payment occurs.

NOTE 3:- SHARE-BASED PAYMENT

The total compensation cost related to all of the Company's equity-based awards, recognized during the presented periods was comprised as follows:

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
Research and development	\$ 969	\$ 799	\$ 376	\$ 172	\$ 705
General and administrative	2,762	1,704	945	708	2,870
	<u>\$ 3,731</u>	<u>\$ 2,503</u>	<u>\$ 1,321</u>	<u>\$ 880</u>	<u>\$ 3,575</u>

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 3:- SHARE-BASED PAYMENT (Cont.)

The Company estimates the fair value of stock options granted using the binominal option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term.

Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected term of the options granted is derived from output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

The following table lists the inputs to the binomial model used for the fair value measurement of equity-settled share options for the above plan for the following periods:

Based on the above inputs, the fair value of the options was determined at \$4.07 - \$11.01 at the grant dates during 2019.

	September 30,		December 31,
	2019	2018	2018
	Unaudited		Audited
Dividend yield (%)	0	0	0
Expected volatility of the share prices (%)	68%-88%	88%-94%	93%-95%
Risk-free interest rate (%)	2.05-2.70	2.17-2.89	2.88-2.63

Movement during the periods:

	Nine months ended September 30,				Year ended December 31,	
	2019		2018		2018	
	Number of options	Weighted average exercise price USD	Number of options	Weighted average exercise price USD	Number of options	Weighted average exercise price USD
Outstanding at beginning of period	3,197,616	3.07	2,467,023	2.28	2,467,023	\$ 2.28
Granted during the period	728,300	9.36	686,977	5.32	751,977	5.60
Expired during the period	-	-	-	-	(2,000)	6.00
Exercised during the period	(477,278)	0.25	(9,692)	0.25	(9,692)	0.25
Forfeited during the period	-	-	(9,692)	0.25	(9,692)	0.25
Share options outstanding at end of period	<u>3,448,638</u>	<u>4.79</u>	<u>3,134,616</u>	<u>2.96</u>	<u>3,197,616</u>	<u>3.07</u>
Share options exercisable at end of period	<u>1,579,378</u>	<u>2.55</u>	<u>1,674,545</u>	<u>1.13</u>	<u>1,705,256</u>	<u>\$ 1.21</u>

As of September 30, 2019, there are \$ 5,034 of total unrecognized costs related to non-vested share based compensation that are expected to be recognized over a period of up to 4 years.

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 4:- LIABILITIES PRESENTED AT FAIR VALUE

- a. Warrants to purchase the Company's shares:

The Company measured the fair value of the warrants by using the option pricing method utilized in a Black- Scholes simulation model. The option pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected time until liquidation. Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected time until liquidation is the period in which a liquidation event will occur subject to the Company's expectations. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

	September 30,		December 31,
	2019	2018	2018
	Unaudited		Audited
Risk-free interest rate	1.57%	2.5%	2.52%
Expected volatility	78%	90%	80%
Expected life (in years)	2.75	2	3.5
Expected dividend yield	0	0	0

- b. Changes in the fair value of warrants classified as Level 3 in the fair value hierarchy:

	Fair value of financial derivatives
Balance at January 1, 2019 (audited)	\$ 24,049
Exercise of warrants	(2,924)
Revaluation of financial derivatives	<u>(15,691)</u>
Balance at September 30, 2019 (unaudited)	<u>\$ 5,434</u>

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 5:- LOSS PER SHARE

- a. Details of the number of shares and loss used in the computation of loss per share:

	Nine months ended September 30, 2019		Three months ended September 30, 2019	
	Weighted number of shares	Loss attributed to equity holders of the Company	Weighted number of shares	Loss attributed to equity holders of the Company
For the computation of basic loss	28,040,507	19,641	33,580,806	10,096
Effect of potential dilutive ordinary shares (Warrants)	518,052	15,689	-	-
For the computation of diluted loss	<u>28,558,559</u>	<u>35,330</u>	<u>33,580,806</u>	<u>10,096</u>

- b. The total weighted number of shares that used for the basic and diluted loss per share calculations, for the nine and three month period ended September 30, 2018 was 689,898 and 690,005, respectively, and for the year ended December 31, 2018 was 5,025,213.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are an advanced cell therapy company committed to cures for blood cancers and serious blood diseases. While cell therapies have the potential to address a variety of diseases, they are limited by availability of donor cells, matching a donor to the patient, and the decline in donor cell functionality when expanding the cells to achieve a therapeutic dose. We have created a novel cell expansion platform, which we call our NAM platform, that is designed to enhance the number and functionality of donor cells in culture. This therapeutic platform leverages the unique properties of nicotinamide to enable the expansion of multiple cell types — including stem cells and natural killer, or NK, cells — with appropriate growth factors to maintain the cells' original phenotype and potency. This may enable the administration of new therapies with the potential to improve treatment outcomes beyond what has been observed with current donor-derived therapies.

Our most advanced product candidate, omidubicel, is an investigational advanced cell therapy designed to enhance and expand the life-saving benefits of hematopoietic stem cell (bone marrow) transplant. The Company is currently enrolling patients in a pivotal Phase 3 clinical trial in approximately 120 patients with various hematologic malignancies, including high risk leukemias such as acute myeloid leukemia, acute lymphocytic leukemia, chronic myeloid leukemia, myelodysplastic syndrome, and lymphomas. We anticipate reporting top-line data from this study in the first half of 2020. In our Phase 1/2 clinical trials, patients who were transplanted with omidubicel achieved rapid engraftment and immune reconstitution, which are key indicators of clinical benefits. In our Phase 1/2 clinical trials, patients who were transplanted with omidubicel achieved rapid engraftment and immune reconstitution, which are key indicators of clinical benefits. Based on the results of our Phase 1/2 clinical trials, we received Breakthrough Therapy Designation for omidubicel in the United States from the U.S. Food and Drug Administration, or the FDA. Furthermore, we received orphan drug designation from both the FDA and the European Medicines Agency.

We are also developing omidubicel for the treatment of other rare, life-threatening hematologic diseases, including severe aplastic anemia, a bone marrow failure disease, which is currently being investigated in a Phase 1/2 trial sponsored by the National Institutes of Health. In addition, we have applied our NAM-based cell expansion technology to NK cells, to develop our product candidate, GDA-201, an investigational, NK cell-based cancer immunotherapy, now being evaluated in a Phase 1 investigator-sponsored trial for the treatment of relapsed or refractory non-Hodgkin lymphoma and multiple myeloma.

We have incurred significant net losses since our formation in 1998. Our net losses were \$19.6 million and \$30.3 million for the nine months ended September 30, 2019 and 2018. As of September 30, 2019, our accumulated deficit was \$188.9 million. We expect to continue to incur losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We expect that our expenses will increase substantially in connection with our ongoing activities as we:

- conduct our international, multicenter, randomized, pivotal Phase 3 clinical trial;
 - continue the preclinical development of our other product candidates;
-

- file a Biologics License Application seeking regulatory approval for any of our product candidates;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any products for which we obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development and commercialization efforts;
- hire additional clinical development, regulatory, commercial, quality control and manufacturing personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization.

We will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. Adequate funding may not be available to us on acceptable terms, or at all.

To continue to fund our operations, we expect to raise capital in addition to the net proceeds of this offering. We may obtain additional financing in the future through the issuance of our ordinary shares, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering and our existing funds will be sufficient to fund our operations through March 2020. However, our ability to successfully transition to profitability will be dependent upon achieving a level of revenue adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Components of Results of Operations

Revenue

We do not currently have any products approved for sale and, to date, we have not recognized any revenue. In the future, we may generate revenue from a combination of product sales, reimbursements, up-front payments and future collaborations. If we fail to achieve clinical success or obtain regulatory approval of any of our product candidates in a timely manner, our ability to generate future revenue will be impaired.

Research and development expenses, net

The largest component of our total operating expenses has historically been, and we expect will continue to be, research and development. Our research and development expenses, net of grants from the Israel Innovation Authority, or IIA, consist primarily of:

- salaries and related costs, including share-based compensation expense, for our personnel in research and development functions;
- expenses incurred under agreements with third parties, including CROs, subcontractors, suppliers and consultants, preclinical studies and clinical trials;
- expenses incurred to acquire, develop and manufacture preclinical study and clinical trial materials; and
- facility and equipment costs, including depreciation expense, maintenance and allocated direct and indirect overhead costs.

Research expenditures are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if we can demonstrate: the technical feasibility of completing the intangible asset so that it will be available for use or sale; our intention to complete the intangible asset and use or sell it; our ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and our ability to measure reliably the expenditure attributable to the intangible asset during its development. Since our development projects are subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not satisfied and, therefore, development expenditures are recognized in profit or loss when incurred.

Through September 30, 2019, we have received grants of approximately \$30.5 million in the aggregate from the IIA for research and development funding. Pursuant to the terms of the grants, we are obligated to pay the IIA royalties, at the rate of between 3% to 4% on all our revenue, up to a limit of 100% of the amounts of the U.S. dollar-linked grants received, plus annual interest calculated at a rate based on 12-month LIBOR. We have not paid any royalties to the IIA to date.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, which will also continue to apply to us following the repayment in full of the amounts due to the IIA. The Innovation Law restricts our ability to manufacture products and transfer technologies outside of Israel and may impair our ability to enter into agreements that involve IIA-funded products or know-how without the approval of the IIA. Any approval, if given, will generally be subject to additional financial obligations by us. Failure to comply with the requirements under the Innovation Law may subject us to mandatory repayment of grants received by us, together with interest and penalties as well as expose us to criminal proceedings.

In June 2017, new rules, or the Licensing Rules, were published by the IIA allowing a grant recipient to enter into licensing arrangements or grant other rights in know-how developed under IIA programs outside of Israel, subject to the prior consent of the IIA and payment of license fees, calculated in accordance with the Licensing Rules. The amount of the license fees is based on various factors, including the consideration received by the licensor in connection with the license, and shall not exceed six times the amount of the grants received by the grants recipient (plus accrued interest) for the applicable know-how being licensed. In certain cases, such as when the license consideration includes nonmonetary compensation or when a "special relationship" exists between the licensor and licensee (*e.g.*, when a party controls the other party or is the other party's exclusive distributor), or when the agreed upon consideration does not reflect, in the IIA's opinion, the market value of the license, the IIA may base the value of the transaction on an economic assessment that it obtains for such purpose. See "Taxation – Material Israeli Tax Considerations" for more information.

Government grants received from the IIA are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing revenue. If no such economic benefits are expected, the grants are recognized as a reduction of the related research and development expenses.

We are currently focused on advancing our product candidates, and our future research and development expenses will depend on their clinical success. Research and development expenses will continue to be significant and will increase over at least the next several years as we continue to develop our product candidates and conduct preclinical studies and clinical trials of our product candidates.

These research and development costs include share-based compensation and other employment costs, regulatory, quality assurance and intellectual property costs. The costs incurred in research and development expenses are to advance the development of our product candidates and preclinical research and development programs. A substantial majority of our research and development expenses are related to the development of omidubicel.

We do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of our product candidates. Due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, if and when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and administrative expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation, related to directors, executive, finance, and administrative functions, facility costs and external professional service costs, including legal, accounting and audit services and other consulting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our administrative headcount and infrastructure to support our continued research and development programs and the potential approval and commercialization of our product candidates. We also anticipate that we will incur increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance premiums, executive compensation, and other customary costs associated with being a public company.

Finance income (expenses), net

Finance income (expenses), net, includes the gain or loss, as applicable, due to revaluation at fair value of warrants and the IIA royalty-bearing grants liability, offset by interest income from deposits and marketable securities.

Income taxes

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$120.5 million (including capital losses of \$0.5 million) as of December 31, 2018. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the unused tax losses can be utilized. As of September 30, 2019, we did not recognize deferred tax assets for carryforward losses because their utilization in the foreseeable future is not probable.

Analysis of Results of Operations

Comparison of the nine months and three months ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months and three months ended September 30, 2019 and 2018:

	Nine months ended September 30,		Three months ended September 30,	
	2019	2018	2019	2018
	(unaudited, in thousands)		(unaudited, in thousands)	
Operating Expenses:				
Research and development expenses, net ⁽¹⁾	\$ 21,682	\$ 17,169	\$ 7,363	\$ 5,132
General and administrative expenses ⁽¹⁾	12,195	7,008	4,621	2,438
Operating loss	33,877	24,177	11,984	7,570
Financial expenses (income), net	(14,166)	6,126	(1,718)	2,252
Loss before taxes on income	19,711	30,303	10,266	9,822
Taxes benefit	(70)	—	(170)	—
Net loss	\$ 19,641	\$ 30,303	\$ 10,096	\$ 9,822

(1) Includes share-based compensation expense as follows:

	Nine months ended September 30,		Three months ended September 30,	
	2019	2018	2019	2018
	(unaudited, in thousands)		(unaudited, in thousands)	
Research and development, net	\$ 969	\$ 799	\$ 376	\$ 172
General and administrative expenses	2,762	1,704	945	708
Total share-based compensation	\$ 3,731	\$ 2,503	\$ 1,321	\$ 880

Research and development expenses

Research and development expenses increased by approximately \$4.5 million to \$21.7 million in the nine months ended September 30, 2019 from \$17.2 million in the nine months ended September 30, 2018. The increase was attributable mainly to a \$3.0 million increase in clinical activities relating to advancing our Phase 3 clinical program and initiation of the GDA-201 clinical program, an increase of \$2.4 million in salaries and benefits, consisting primarily of additional headcount focused on clinical development, a decrease of \$1.3 million in royalty-bearing grants from the IIA, and an increase of \$0.4 million in other expenses.

General and administrative expenses

General and administrative expenses increased by approximately \$5.2 million to \$12.2 million in the nine months ended September 30, 2019, from \$7.0 million in the nine months ended September 30, 2018. The increase was attributable mainly to a \$1.4 million increase in salaries and benefits as a result of hiring key C-level executives and establishing our US headquarters, an increase of \$1.1 million in non-cash stock-based compensation expenses, a \$1.1 million increase in commercial activities, and \$1.2 million increase in professional services expenses, insurance, board fee, legal and other expenses incurred as a result of becoming a public company, and a \$0.4 million increase in other expenses.

Finance expenses, net

Finance expenses, net, increased by approximately \$20.3 million to \$14.2 million of income in the nine months ended September 30, 2019, from \$6.1 million of expenses in the nine months ended September 30, 2018, primarily due to non-cash expenses resulting from revaluation of warrants and the revaluation of IIA royalty-bearing grant liability.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred losses and negative cash flows from our operations. For the nine months ended September 30, 2019, we incurred net losses of \$19.6 million, and net cash used of \$26.6 million, was used in our operating activities. As of September 30, 2019 we had working capital of \$60.1 million, and an accumulated deficit of \$188.9 million. Our principal sources of liquidity as of September 30, 2019 consisted of cash and cash equivalents, available-for-sale financial assets and short-term deposits of \$68.1 million.

Capital resources

Overview

Through September 30, 2019, we have financed our operations primarily through private placements of equity securities and through the grants received from the IIA. Since November 2018, we have also financed our operations through the proceeds of our public offerings.

Cash flows

The following table summarizes our statement of cash flows for the nine months ended September 30, 2019 and 2018:

	Nine months ended September 30,	
	2019	2018
	(unaudited, in thousands)	
Net cash provided by (used in)		
Operating activities	\$ (26,608)	\$ (18,318)
Investing activities	(10,371)	8,885
Financing activities	36,175	2,217

Net cash used in operating activities

The cash used in operating activities during the aforementioned periods resulted primarily from our net losses incurred during such periods, as adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net losses for non-cash items mainly consisted of fair value adjustment of warrants, revaluation of the liability to the IIA and share-based compensation.

Net cash used in operating activities was \$26.6 million during the nine months ended September 30, 2019, compared to \$18.3 million used in operating activities during the nine months ended September 30, 2018. The \$8.3 million increase in cash used was attributable primarily due to an increase in our cash burn rate from operating activities.

Net cash provided by (used in) investing activities

Net cash used in investing activities was \$10.4 million during the nine months ended September 30, 2019, compared to \$8.9 million provided during the nine months ended September 30, 2018. The \$19.3 million decrease in cash provided is primarily related to the sale and maturity of available for sale assets and bank deposits during 2018 and investment in available for sale assets and bank deposits during 2019, and purchase of equipment.

Net cash provided by financing activities

Net cash provided by financing activities was \$36.2 million during the nine months ended September 30, 2019, compared to \$2.2 million provided by financing activities during the nine months ended September 30, 2018. The increase is primarily related to \$37.1 million in proceeds from the issuance of our ordinary shares, net of issuance expenses, offset by lease liabilities resulting from implementation of IFRS 16.

For Release Wednesday, November 13, 2019, at 4:01 P.M. ET

Gamida Cell Reports Third Quarter 2019 Financial Results and Provides Company Update

– Completion of patient enrollment in Phase 3 clinical study of omidubicel expected by year-end; Topline data anticipated in first half of 2020 –

– Additional results from Phase 1 study of GDA-201 and new data on NAM technology platform to be presented at 61st Annual Meeting of the American Society of Hematology –

Boston, Mass. – Nov. 13, 2019 – Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases, today reported financial results for the quarter ended September 30, 2019. The company also highlighted continued progress in advancing its clinical development candidates: omidubicel, an advanced cell therapy in Phase 3 clinical development as a potential life-saving treatment option for patients in need of bone marrow transplant, and GDA-201, an investigational, natural killer (NK) cell-based cancer immunotherapy in Phase 1 development in patients with non-Hodgkin lymphoma and multiple myeloma.

“During the quarter, we made important progress toward our goal of developing next-generation cell therapies with the potential to redefine standards of care for patients with blood cancers and rare, serious hematologic diseases,” stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. “We are nearing completion of patient enrollment in our multi-center, randomized Phase 3 study of omidubicel and are on track to report topline data from the study in the first half of 2020. Positive data from the study would enable us to file our first biologics license application next year.”

“Our second cell therapy program, GDA-201, is also advancing, and next month we will report additional data from the ongoing Phase 1 study at the Annual Meeting of the American Society of Hematology,” Dr. Adams continued. “During the meeting, we will also show new gene expression data that reinforce our understanding of the mechanism of action underlying our NAM technology platform which enabled the generation of both of our development candidates.”

Program Highlights

- **Announced presentation of new data at the 61st Annual Meeting of the American Society of Hematology (ASH):** Last week, Gamida Cell announced that additional data from the ongoing Phase 1 clinical study of GDA-201 will be presented during an oral session at the ASH 2019 Annual Meeting, which is being held December 7 – 10 in Orlando, FL. The presentation, “Results of a Phase 1 Trial of GDA-201, Nicotinamide-Expanded Allogeneic Natural Killer Cells (NAM-NK) in Patients with Refractory Non-Hodgkin Lymphoma (NHL) and Multiple Myeloma (MM)” (Abstract #777), will take place on Monday, December 9, at 3:15 p.m. ET.

Additionally, new research on the mechanism of action of Gamida Cell's NAM-based cell expansion platform, which is designed to enhance the number and functionality of allogeneic donor cells, will also be shared during the meeting. The poster presentation, "Nicotinamide (NAM) Modulates Transcriptional Signature of *Ex Vivo* Cultured UCB CD34+ Cells (Omidubicel) and Preserves Their Stemness and Engraftment Potential" (Abstract #3718), will take place on Monday, December 9, from 6:00 – 8:00 p.m. ET.

- **Advanced the Phase 3 clinical study of omidubicel:** Patient enrollment continued to progress in the Gamida Cell's Phase 3 study of omidubicel in patients with high-risk hematologic malignancies. The international, randomized, multi-center study is designed to evaluate the safety and efficacy of omidubicel compared to standard umbilical cord blood for allogeneic bone marrow transplant in approximately 120 patients with no available matched donor. The company anticipates completing patient enrollment by the end of this year with topline data anticipated in first half of 2020.
- **Initiated health outcomes research for omidubicel:** In September, Gamida Cell and the CIBMTR® (Center for International Blood and Marrow Transplant Research) announced a research agreement to evaluate outcomes of patients with hematological malignancies who undergo allogeneic hematopoietic stem cell transplant (bone marrow transplant) from various donor sources. The recently launched observational study includes both retrospective and prospective data contemporaneous to the Phase 3 study of omidubicel. The goal of this real-world, observational study is to better understand the variables that influence the health outcomes of patients receiving a transplant from a source other than a fully matched family donor.
- **Continued to focus on activities required to successfully bring omidubicel to patients:** Gamida Cell is continuing to advance key activities required to bring omidubicel to patients in a commercial setting, including building out manufacturing infrastructure, assembling an experienced commercial team with expertise in cell therapy and transplant, establishing hospital services and patient assistance programs, and exploring coverage and reimbursement models to enable access.
- **Progressed enrollment in the Phase 1/2 study of omidubicel in patients with severe aplastic anemia:** Enrollment is ongoing in a Phase 1/2 clinical study of omidubicel in patients with severe aplastic anemia, a rare, life-threatening bone marrow failure disease. Earlier this year, encouraging data from the first cohort of patients were reported at the 2019 Transplantation & Cellular Therapy (TCT) Meeting that demonstrated that all three patients in the cohort successfully underwent a bone marrow transplant consisting of omidubicel plus a haploidentical stem cell graft. The rapid engraftment, sustained hematopoiesis and accelerated immune recovery observed enabled the initiation of a second cohort, where patients will be treated with omidubicel as a stand-alone graft.
- **Continued to prepare for the next clinical study of GDA-201:** The company is continuing its work to enable a Phase 1/2 multi-dose, multi-center study of GDA-201 in patients with non-Hodgkin lymphoma, which is expected to begin in 2020. The decision to focus the next clinical study on non-Hodgkin lymphoma is based on the encouraging clinical data reported at the 2019 TCT Meeting which demonstrated the GDA-201 was generally well tolerated and clinically active, with multiple complete responses observed.

Third Quarter 2019 Financial Results

- Research and development (R&D) expenses in the third quarter of 2019 were \$7.4 million compared to \$5.1 million for the same period in 2018. R&D expenses were higher in the third quarter of 2019 compared to the same period in 2018 due to the advancement of omidubicel and GDA-201.
- General and administrative expenses were \$4.6 million for the third quarter of 2019, compared to \$2.4 million for the same period in 2018. The difference was attributable mainly to a \$1.2 million increase in activities related to commercial readiness, as well as \$1.0 million increase in professional services and other expenses, including an increase in expenses associated with being a publicly-traded company.
- Finance income, net, was \$1.7 million for the third quarter of 2019, compared to finance expenses, net, of \$2.2 million for the same period in 2018. The net increase was primarily due to non-cash income resulting from the re-valuation of warrants, offset by non-cash expenses from the re-valuation of the Israeli Innovation Authority royalty-bearing grant liability.
- Net loss for the third quarter of 2019 was \$10.1 million, compared to a net loss of \$9.8 million for the same period in 2018.
- As of September 30, 2019, Gamida Cell had total cash, cash equivalents and available-for-sale assets of \$68.1 million, compared to \$60.7 million as of December 31, 2018.

2019 Financial Guidance

Gamida Cell continues to expect cash used for ongoing operating activities in 2019 to range from \$35 million to \$40 million, reflecting anticipated expenditures to advance the company's clinical programs.

Gamida Cell expects that its current cash, cash equivalents and available-for-sale securities will support the company's ongoing operating activities into the fourth quarter of 2020. This cash runway guidance is based on the company's current operational plans and excludes any additional funding that may be received or business development activities that may be undertaken.

Conference Call Information

Gamida Cell will host a conference call today, November 13, 2019, at 4:30 p.m. ET to discuss these financial results and company updates. A live webcast of the conference call can be accessed in the "Investors" section of Gamida Cell's website at www.gamida-cell.com. To participate in the live call, please dial 866-930-5560 (domestic) or 409-216-0605 (international) and refer to conference ID number 8653335. A replay of the webcast will be available approximately two hours after the event, for approximately 30 days.

About Omidubicel

Omidubicel (formerly known as NiCord[®]), the company's lead clinical program, is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with hematologic malignancies (blood cancers).¹ Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration and has also received Orphan Drug Designation in the U.S. and EU. In a Phase 1/2 clinical study, omidubicel demonstrated rapid and durable time to engraftment and was generally well-tolerated.¹ A Phase 3 study evaluating omidubicel in patients with leukemia and lymphoma is ongoing in the U.S., Europe and Asia.² Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia.³ The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn[®], which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

¹Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. *J Clin Oncol.* 2019 Feb 10;37(5):367-374.

²ClinicalTrials.gov identifier NCT02730299.

³ClinicalTrials.gov identifier NCT03173937.

About GDA-201

Gamida Cell applied the capabilities of its NAM-based cell expansion technology to develop GDA-201 (formerly known as NAM-NK), an innate natural killer (NK) cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs of NK cells expanded in culture. GDA-201 is in Phase 1 development through an investigator-sponsored study in patients with refractory non-Hodgkin lymphoma and multiple myeloma.⁴

Omidubicel and GDA-201 are investigational therapies, and their safety and efficacy have not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About Gamida Cell

Gamida Cell is an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit www.gamida-cell.com.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to the patient enrollment in and timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, and Gamida Cell's expectations regarding its projected operating expenses and cash runway, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and variability, and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of Gamida Cell's public filing on Form 20-F, filed with the SEC on February 25, 2019, and other filings that Gamida Cell makes with the SEC from time to time (which are available at <http://www.sec.gov>), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

Contacts:

Jaren Irene Madden
jaren@gamida-cell.com
1-617-286-6264

Krystle Gibbs (media)
krystle@tenbridgecommunications.com
508-479-6358

⁴ClinicalTrials.gov identifier NCT03019666.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands

	September 30,		Dec 31,
	2019	2018	2018
	Unaudited		Audited
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 39,573	\$ 14,109	\$ 40,272
Available-for-sale financial assets	28,544	9,570	20,417
Prepaid expenses and other current assets	1,134	1,018	1,502
Total current assets	69,251	24,697	62,191
NON-CURRENT ASSETS:			
Property and equipment, net	4,209	1,743	2,311
Right-of-use assets	5,568	-	-
Other assets	651	354	662
Deferred issuance cost	-	1,718	-
Total non-current assets	10,428	3,815	2,973
Total assets	\$ 79,679	\$ 28,512	\$ 65,164
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	\$ 2,105	\$ 3,060	\$ 1,985
Employees and payroll accruals	3,096	2,128	2,888
Current maturities of lease liabilities	1,926	-	-
Accrued expenses and other payables	1,979	2,111	1,832
Total current liabilities	9,106	7,299	6,705
NON-CURRENT LIABILITIES:			
Liabilities presented at fair value	5,434	15,400	24,049
Employee benefit liabilities, net	280	194	183
Lease liability	4,342	-	-
Liability to Israel Innovation Authority (IIA)	11,594	10,474	9,540
Total non-current liabilities	21,650	26,068	33,772
SHAREHOLDERS' EQUITY:			
Total shareholders' equity	48,923	(4,855)	24,687
Total liabilities and shareholders' equity	\$ 79,679	\$ 28,512	\$ 65,164

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

U.S. dollars in thousands (except share and per share data)

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
Operating expenses:					
Research and development, net	\$ 21,682	\$ 17,169	\$ 7,363	\$ 5,132	\$ 22,045
General and administrative	12,195	7,008	4,621	2,438	11,599
Operating loss	33,877	24,177	11,984	7,570	33,644
Finance expenses	2,499	6,560	895	2,356	20,259
Finance income	(16,665)	(434)	(2,613)	(104)	(1,042)
Loss (income) before taxes on income	19,711	30,303	10,266	9,822	52,861
Taxes on income (benefit)	(70)	-	(170)	-	70
Net loss	19,641	30,303	10,096	9,822	52,931
Net loss (income) per share:					
Basic net loss per share	\$ 0.70	\$ 43.92	\$ 0.30	\$ 14.23	\$ 10.53
Diluted net loss per share	\$ 1.24	\$ 43.92	\$ 0.30	\$ 14.23	\$ 10.53

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
Cash flows from operating activities:					
Net loss	\$ (19,641)	\$ (30,303)	\$ (10,096)	\$ (9,822)	\$ (52,931)
Adjustments to reconcile net loss to net cash used in operating activities:					
Adjustments to the profit or loss items:					
Depreciation of property, plant and equipment and right-of-use assets	1,792	146	547	49	269
Financial (income) expenses, net	(768)	(161)	(199)	214	(858)
Cost of share-based compensation	3,731	2,503	1,321	880	3,575
Change in employee benefit liabilities, net	14	(6)	6	(23)	(15)
Amortization of premium on available-for-sale financial assets	150	191	49	200	272
Revaluation of financial derivatives	(15,691)	5,100	(2,220)	1,700	17,600
Revaluation of liability to IIA	1,852	3,167	653	567	2,037
	<u>(8,920)</u>	<u>10,940</u>	<u>157</u>	<u>3,587</u>	<u>22,880</u>
Changes in asset and liability items:					
Decrease (increase) in prepaid expenses and other current assets and other assets	113	(1,266)	(4)	(1,637)	942
Increase (decrease) in trade payables	120	670	(124)	1,902	(405)
Increase (decrease) in accrued expenses and other payables and employee and payroll accrual	680	1,071	518	(8)	2,296
	<u>913</u>	<u>475</u>	<u>390</u>	<u>257</u>	<u>2,833</u>
Cash received during the period for:					
Interest received	1,132	570	302	179	792
Interest paid	(92)	-	(41)	-	-
	<u>1,040</u>	<u>570</u>	<u>261</u>	<u>179</u>	<u>792</u>
Net cash used in operating activities	<u>(26,608)</u>	<u>(18,318)</u>	<u>(9,288)</u>	<u>(5,799)</u>	<u>(26,426)</u>
Cash flows from investing activities:					
Purchase of property and equipment	(2,139)	(949)	(1,261)	(246)	(1,645)
Purchase of available-for-sale financial assets	(32,021)	-	(32,021)	-	(10,905)
Proceed from sale of available-for-sale financial assets	-	4,984	-	-	4,949
Proceed from maturity of available-for-sale financial assets	23,789	-	8,049	-	-
Proceeds from bank deposits	-	5,000	-	-	5,000
Investment in restricted bank deposits	-	(150)	-	(150)	(150)
Net cash provided by (used in) investing activities	<u>(10,371)</u>	<u>8,885</u>	<u>(25,233)</u>	<u>(396)</u>	<u>(2,751)</u>

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				
<u>Cash flows from financing activities:</u>					
Proceeds from secondary offering, net	37,235	-	37,343	-	-
Receipt of grants from the IIA	202	2,953	35	1,300	612
Proceeds from issuance of shares, initial public offering (payment of issuance expenses), net	(238)	-	-	-	47,479
Payment of lease liabilities	(1,144)	-	(380)	-	-
Exercise of options	120	-	3	-	2
Increase in deferred issuance cost	-	(736)	-	-	-
Net cash provided by financing activities	<u>36,175</u>	<u>2,217</u>	<u>37,001</u>	<u>1,300</u>	<u>48,093</u>
Exchange differences on balances of cash and cash equivalents	105	-	15	-	31
Increase (decrease) in cash and cash equivalents	(699)	(7,216)	2,495	(4,895)	18,947
Cash and cash equivalents at beginning of period	<u>40,272</u>	<u>21,325</u>	<u>37,078</u>	<u>19,004</u>	<u>21,325</u>
Cash and cash equivalents at end of period	<u>\$ 39,573</u>	<u>\$ 14,109</u>	<u>\$ 39,573</u>	<u>\$ 14,109</u>	<u>\$ 40,272</u>