

Advanced Biomedical Technologies Inc.  
Form 10-Q  
April 01, 2019

**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 quarter ended January 31, 2019**

**OR**

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

**Commission file number 000-53051**

**Advanced BioMedical Technologies, Inc.**  
(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction of incorporation or organization)

**350 Fifth Avenue, 59th Floor**  
**New York, NY 10118**  
(Address of principal executive offices, including zip code.)

**(718) 766-7898**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

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

As of April 1, 2019, there are 69,624,850 shares of common stock outstanding.

All references in this Report on Form 10-Q to the terms "we", "our", "us", the "Company", "ABMT" and the "Registrant" refer to Advanced BioMedical Technologies, Inc. unless the context indicates another meaning.

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**PART I – FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

The accompanying condensed consolidated unaudited financial statements of Advanced BioMedical Technologies, Inc., a Nevada corporation are condensed and, therefore, do not include all disclosures normally required by accounting principles generally accepted in the United States of America. These statements should be read in conjunction with the Company's most recent annual financial statements for the year ended October 31, 2018 included in our Annual Report on Form 10-K/A filed with the U.S. Securities and Exchange Commission ("SEC") on March 29, 2019. In the opinion of management, all adjustments necessary for a fair presentation have been included in the accompanying condensed consolidated financial statements and consist of only normal recurring adjustments. The results of operations presented in the accompanying condensed consolidated financial statements for the period ended January 31, 2019 are not necessarily indicative of the operating results that may be expected for the full year ending October 31, 2019.

ADVANCED BIOMEDICAL TECHNOLOGIES, INC.

AND SUBSIDIARIES

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF JANUARY 31, 2019

(UNAUDITED)

ADVANCED BIOMEDICAL TECHNOLOGIES, INC.

AND SUBSIDIARIES

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## ADVANCED BIOMEDICAL TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	January 31, 2019 (Unaudited)	October 31, 2018
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$16,945	\$6,860
Other receivables and prepaid expenses	44,947	32,649
Total Current Assets	61,892	39,509
Property and equipment, cost	550,368	521,120
Less: Accumulated depreciation	(440,202 )	(418,225 )
<b>PROPERTY AND EQUIPMENT, NET</b>	<b>110,166</b>	<b>102,895</b>
<b>DEPOSIT FOR PURCHASE OF PROPERTY AND EQUIPMENT</b>	<b>17,516</b>	<b>-</b>
<b>TOTAL ASSETS</b>	<b>\$189,574</b>	<b>\$142,404</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Other payables and accrued expenses	\$516,757	\$443,163
Due to directors	277,628	273,874
Due to a stockholder	762,147	718,808
Due to related parties	4,713,073	4,325,571
Total Current Liabilities	6,269,605	5,761,416
<b>STOCKHOLDERS' DEFICIT</b>		
Common stock, \$0.00001 par value, 100,000,000 shares authorized, 69,624,850 issued and outstanding as of January 31, 2019 and October 31, 2018	696	696
Additional paid-in capital	2,743,331	2,740,183
Accumulated deficit	(8,885,141)	(8,632,618)
Accumulated other comprehensive income/(loss)	61,083	272,727
Total Deficit	(6,080,031)	(5,619,012)
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$189,574</b>	<b>\$142,404</b>

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





## ADVANCED BIOMEDICAL TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

	3 months ended	
	January 31, 2019	January 31, 2018
<b>OPERATING EXPENSES</b>		
General and administrative expenses	\$ 147,930	\$ 121,672
Depreciation	5,000	2,179
Research and development	16,979	15,770
Total Operating Expenses	169,909	139,621
<b>LOSS FROM OPERATIONS</b>	(169,909 )	(139,621 )
<b>OTHER (EXPENSES) INCOME</b>		
Interest income	10	7
Interest paid to a stockholder and related parties	(75,507 )	(67,546 )
Imputed interest	(3,148 )	(3,844 )
Other, net	(3,969 )	(11,539 )
Total Other (Expenses) Income, net	(82,614 )	(82,922 )
<b>LOSS BEFORE TAXES</b>	(252,523 )	(222,543 )
Income tax expense	-	-
<b>NET LOSS</b>	(252,523 )	(222,543 )
Net loss attributable to non-controlling interests	-	-
<b>NET LOSS ATTRIBUTABLE TO ABMT COMMON STOCKHOLDERS</b>	(252,523 )	(222,543 )
<b>OTHER COMPREHENSIVE INCOME</b>		
Foreign currency translation income	(211,644 )	(255,418 )
Total other comprehensive gain/(loss)	(211,644 )	(255,418 )
<b>COMPREHENSIVE GAIN/(LOSS) ATTRIBUTABLE TO ABMT COMMON STOCKHOLDERS</b>	\$(464,167 )	\$(477,961 )
Net loss per share-basic and diluted		
- basic and diluted	\$(0.00 )	\$(0.00 )
Weighted average number of shares outstanding during the		
- basic and diluted	69,430,102	69,374,850

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

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## ADVANCED BIOMEDICAL TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT (UNAUDITED)

	Common stock Number of shares	Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance at October 31, 2016	67,124,850	\$ 671	\$2,520,520	\$(6,987,698 )	\$ 104,212	\$(4,362,295)
Stock issued for debt conversion at 0.05 per share	2,000,000	20	99,980	-	-	100,000
Stock issued for services (\$0.15 per share)	250,000	3	37,497	-	-	37,500
Imputed interest on advances from directors	-	-	15,623	-	-	15,623
Net loss for the year	-	-	-	(691,600 )	-	(691,600 )
Foreign currency translation loss	-	-	-	-	(94,255 )	(94,255 )
Balance at October 31, 2017	69,374,850	\$ 694	\$2,673,620	\$(7,679,298 )	\$ 9,957	\$(4,995,027)
Stock issued for services (\$0.211 per share)	250,000	2	52,748	-	-	52,750
Imputed interest on advances from directors	-	-	13,815	-	-	13,815
Net loss for the year	-	-	-	(953,320 )	-	(953,320 )
Foreign currency translation loss	-	\$ -	\$-	\$-	\$ 262,770	\$262,770
Balance at October 31, 2018	69,624,850	\$ 696	2,740,183	\$(8,632,618 )	\$ 272,727	\$(5,619,012)
Imputed interest on advances from directors	-	-	3,148	-	-	3,148
Net loss for the period	-	\$ -	-	(252,523 )	-	(252,523 )
Foreign currency translation loss	-	\$ -	-	\$-	(211,644 )	(211,644 )
Balance at January 31, 2019	69,624,850	\$ 696	\$2,743,331	\$(8,885,141 )	\$ 61,083	\$(6,080,031)

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

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## ADVANCED BIOMEDICAL TECHNOLOGIES, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	3 months ended January 31,	
	2019	2018
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss attributable to ABMT common stockholders	(252,523)	\$(222,543)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	5,000	2,179
Imputed interest	3,148	3,844
Changes in operating assets and liabilities		
Decrease (increase) in:		
Other receivables and prepaid expenses	(11,020 )	(2,220 )
Increase in:		
Other payables and accrued expenses	55,628	(9,591 )
Net cash used in operating activities	(199,767)	(228,331)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(7,968 )	(4,457 )
Renovation of factory premises	(17,075 )	
(Increase) decrease in deposit for purchase of property and equipment	-	-
Net cash used in investing activities	(25,043 )	(4,457 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Due to a stockholder	43,428	48,021
Due to directors	(6,552 )	3,602
Due to related parties	197,746	191,832
Net cash provided by financing activities	234,622	243,455
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	273	639
<b>NET INCREASE / (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	10,085	11,306
<b>CASH AND CASH EQUIVALENTS AT THE BEGINNING OF YEAR</b>	6,860	7,463
<b>CASH AND CASH EQUIVALENTS AT THE END OF YEAR</b>	16,945	\$18,769
<b>Supplemental of cash flow information</b>		
Interest income	\$10	\$7
Other non cash items		
Interest expenses	\$75,507	\$67,546

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

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ADVANCED BIOMEDICAL TECHNOLOGIES, INC.  
AND SUBSIDIARIES

NOTES TO THE CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS (UNAUDITED)

**NOTE 1 BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

In the opinion of management, the unaudited condensed consolidated financial statements contain adjustments considered necessary to present fairly the Company’s financial position as of January 31, 2019, the consolidated results of operations for the three months ended January 31, 2019 and 2018 and consolidated statements of cash flows for the three months ended January 31, 2019 and 2018 on an accrual basis and in accordance with accounting principles generally accepted in the United States of America for interim financial information and rules and regulations of the SEC. The consolidated results for the three months ended January 31, 2019 are not necessarily indicative of the results to be expected for the entire fiscal year ending October 31, 2019. These consolidated financial statements should be read in conjunction with the consolidated financial statements and notes for the year ended October 31, 2018 appearing in the Company’s annual report on Form 10-K/A as filed with the Securities and Exchange Commission on March 29, 2019.

The reporting currency of the Company is US dollar.

**NOTE 2 ORGANIZATION**

Advanced BioMedical Technologies, Inc. (fka “Geostar Mineral Corporation” or “Geostar”) (“ABMT”) was incorporated in Nevada on September 12, 2006.

Shenzhen Changhua has been involved in the development of polymer screws, rods and binding wires for fixation on human fractured bones. The Company is currently involved in researching, manufacturing and conducting clinical trials on its products and intends to raise additional capital to produce and market its products commercially. The Company holds one Class III permit and one Class II permit from the China Food and Drug Administration (“CFDA”), formally the State Food and Drug Administration (“SFDA”) of the PRC. The Company holds two patents issued by the State Intellectual Property Office of the P.R.C. (“SIPO”). The Company has no revenue since its inception and, in accordance with Accounting Standards Codification (“ASC”) Topic 915, “Development Stage Entities” (formerly Statement of Financial Accounting Standard (“SFAS”) No. 7, “Accounting and Reporting by Development Stage Enterprise”), is considered a Development Stage Company.

Masterise Holdings Limited (“Masterise”) was incorporated in the British Virgin Islands on May 31, 2007 as an investment holding company and was then owned as to 63% by the spouse of Shenzhen Changhua’s 70% majority stockholder at the time and 37% by a third party corporation.

On January 29, 2008, Masterise entered into a Share Purchase Agreement (“the Agreement”) with a stockholder of Shenzhen Changhua whereupon Masterise acquired 70% of Shenzhen Changhua for US\$64,100 in cash. The acquisition was completed on February 25, 2008. As both Masterise and Shenzhen Changhua were under common control and management, the acquisition was accounted for as a reorganization of entities under common control. Accordingly, the operations of Shenzhen Changhua were included in the consolidated financial statements as if the transactions had occurred retroactively.



On December 31, 2008, ABMT consummated a Share Exchange Agreement (“the Exchange Agreement”) with the stockholders of Masterise pursuant to which ABMT issued 50,000 shares of Common Stock to the stockholders of Masterise for 100% equity interest in Masterise.

Concurrently, on December 31, 2008, a major stockholder of ABMT also consummated an Affiliate Stock Purchase Agreement (the “Affiliate Agreement”) with thirteen individuals including all the stockholders of Masterise, pursuant to which the major stockholder sold a total of 5,001,000 shares of ABMT’s common stock for a total aggregate consideration of \$5,000, including 4,438,250 shares to the stockholders of Masterise.

On consummation of the Exchange Agreement and the Affiliate Agreement, the 70% majority stockholder of Masterise became an 80.7% stockholder of ABMT.

On March 13, 2009, the name of the Company was changed from Geostar Mineral Corporation to Advanced Biomedical Technologies, Inc.

The merger of ABMT and Masterise was treated for accounting purposes as a capital transaction and recapitalization by Masterise (“the accounting acquirer”) and a re-organization by ABMT (“the accounting acquiree”). The financial statements have been prepared as if the re-organization had occurred retroactively.

Accordingly, these financial statements include the following:

- (1) The balance sheet consisting of the net assets of the acquirer at historical cost and the net assets of the acquiree at historical cost.
- (2) The statement of operations including the operations of the acquirer for the periods presented and the operations of the acquiree from the date of the transaction.

ABMT, Masterise and Shenzhen Changhua are hereinafter referred to as (“the Company”).

### **NOTE 3 PRINCIPLES OF CONSOLIDATION**

The accompanying condensed consolidated financial statements include the financial statements of ABMT and its wholly owned subsidiaries, Masterise and its 70% owned subsidiary, Shenzhen Changhua. The non-controlling interests in periods prior to 2012 represent the non-controlling stockholders' 30% proportionate share of the results of Shenzhen Changhua.

All significant inter-company balances and transactions have been eliminated in consolidation.

#### **NOTE 4 USE OF ESTIMATES**

The preparation of the 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 amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### **NOTE 5 RELATED PARTY TRANSACTIONS**

As of January 31, 2019 and October 31, 2018, the Company owed a stockholder \$762,147 and \$718,808 respectively which are unsecured and repayable on demand. Interests are charged at 7% per annum on the amount owed.

As of January 31, 2019 and October 31, 2018, the Company owed four related parties a total of \$4,713,073 and \$4,325,571 respectively which are unsecured and repayable on demand. Interests are charged at 7% per annum on the amounts owed.

Total interest expenses on advances from a stockholder and the related parties accrued for the three months ended January 31, 2019 and 2018 were \$75,507 and \$67,546 respectively.

As of January 31, 2019 and October 31, 2018, the Company owed \$277,628 and \$273,874 respectively, to two directors for advances made on an unsecured basis, repayable on demand and interest free.

Imputed interest charged at 5% per annum on the amounts owed to two directors is \$3,148 and \$3,844 for the three months ended January 31, 2019 and 2018 respectively.

## **NOTE 6 COMMITMENTS AND CONTINGENCIES**

### Operating Lease

The Company's existing rental leases do not contain significant restrictive provisions. The following is a schedule by year of future minimum lease obligations under non-cancelable rental operating leases which fall due as follows:

Fiscal years ending October 31, 2019	30,467
Fiscal years ending October 31, 2020	35,843
Fiscal years ending October 31, 2021	14,935
Total	\$81,245

### Investment in Production Equipment

The Company has committed to invest in production equipment up to US\$32,588, of which US\$17,516 has been paid and reflected under Deposit for Purchase of Property and Equipment, with US\$15,072 remains as outstanding commitment.

## **NOTE 7 FAIR VALUE OF FINANCIAL INSTRUMENTS**

The Financial Accounting Standards Board (FASB) Codification Topic 825 (ASC Topic 825), "Disclosure About Fair Value of Financial Instruments," requires certain disclosures regarding the fair value of financial instruments. The carrying amounts of other receivables and prepaid expenses, other payables and accrued liabilities and due to a

stockholder, directors and related parties approximate their fair values because of the short-term nature of the instruments. The management of the Company is of the opinion that the Company is not exposed to significant interest or credit risks arising from these financial statements.

## **NOTE 8 RECENT ACCOUNTING PRONOUNCEMENTS**

There has been no newly effective accounting pronouncement that has significance, or potential significance, to our consolidated financial statements.

### **Accounting Pronouncements Not Yet Effective**

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”), which modifies lease accounting for lessees to increase transparency and comparability by recording lease assets and liabilities for operating leases and disclosing key information about leasing arrangements. The new standard, as amended by ASU 2018-01, ASU 2018-10, ASU 2018-11 and ASU 2019-01, is effective for annual periods beginning after December 15, 2018 on a modified retrospective basis. The Company will adopt ASU 2016-02 in its first quarter of the year ending October 31 2020. The Company expects its leases designated as operating leases in Note 6, “Commitments and Contingencies,” will be reported on the consolidated balance sheets upon adoption. However, the ultimate impact of adopting ASU 2016-02 will depend on the lease terms as of the adoption date.

The Company has reviewed all other recently issued, but not yet effective, accounting pronouncements and do not believe the future adoptions of any such pronouncements may be expected to cause a material impact on the financial condition or the results of operations.

## **NOTE 9 GOING CONCERN**

As reflected in the accompanying unaudited condensed consolidated financial statements, the Company has not commenced revenue producing operations and has an accumulated deficit of \$8,885,141 as of January 31, 2019 that includes a net loss of \$252,523 for the three months ended January 31, 2019. As of January 31, 2019, the Company’s total current liabilities exceeded its total current assets by \$6,207,713 and the Company used cash in operations of \$199,767 for the three months ended on that date. These factors raise substantial doubt about its ability to continue as a going concern. In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying condensed consolidated balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company’s ability to raise additional capital, obtain financing and succeed in its future operations. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Management has taken the following steps to revise its operating and financial requirements, which it believes are sufficient to provide the Company with the ability to continue as a going concern. The Company is actively pursuing additional funding and strategic partners, which will enable the Company to implement its business plan. Management believes that these actions as successful will allow the Company to continue its operations through the next fiscal year.

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

### **Forward Looking Statements**

This section of the report includes a number of forward-looking statements that reflect our current views with respect to future events and financial performance. Forward-looking statements are often identified by words like: believe, expect, estimate, anticipate, intend, project and similar expressions, or words which, by their nature, refer to future events. Actual results could differ materially from those anticipated in these forward looking statements as a result of any number of factors, including those set forth in this Quarterly Report, and in the Company's most recent Annual Report on Form 10-K/A filed on March 29, 2019.

All written and oral forward-looking statements made in connection with this Quarterly Report on Form 10-Q that are attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Given the uncertainties that surround such statements, you are cautioned not to place undue reliance on such forward-looking statements, which apply only as of the date of this quarterly report. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or our predictions.

### **Overview**

The following discussion is an overview of the important factors that management focuses on in evaluating our businesses, financial condition and operating performance and should be read in conjunction with the financial statements included in this Quarterly Report on Form 10-Q.

The Company is subject to a number of risks similar to other companies in the medical device industry. These risks include but are not limited to rapid technological change, uncertainty of market acceptance of our products, uncertainty of regulatory approval, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulation, protection of proprietary technology, product liability, and the dependence on key individuals.

### **Our Business**

We are engaged in the business of designing, developing, manufacturing and marketing of biomaterial internal fixation devices. We hold one Class III medical device permit for our product - polymer orthopaedic internal fixation screws and one Class II permit from the China Food and Drug Administration (“CFDA”). We hold two patents issued by the State Intellectual Property Office of the P.R.C. (“SIPO”). Our polyamide materials, their uses and manufacturing processes are protected by Patent No. ZL971190739. A new patent, No. ZL201410647464.1 titled “Bone Fracture Plate Made of High Polymer Materials” was granted to us in January 2018. Our polyamide materials are used in producing screws, binding wires, rods and related products. These products are used in a variety of applications including orthopedic trauma, sports related medical treatment, or cartilage injuries, and reconstructive dental procedures. At this time, our company is the sole patent holder and market permit holder of PA technologies in China, as well as the only company currently engaged in clinical trials, manufacturing and marketing for PA orthopaedic internal fixation devices in the PRC. Our products are made of a very unique material called PA6-P(MMA-CO-NVP)-HA (“PA”). Our PA products, such as screws, binding wires, rods, suture anchors and rib-pins consist of enhanced fibers and high molecular polymers which are designed to facilitate quick healing of complex fractures in many areas of the human skeletal system.

Our products offer a number of significant advantages over existing metal implants and the first generation of degradable implants (i.e. PLLA) for patients, surgeons and other customers including:

1. A notably reduced need for a secondary surgery to remove implant due to post-operative complications, therefore avoiding unnecessary risk and expense on all patient care;
2. Enhancing the performance of the materials by manufacturing them to be easily fitted to each patient, forming an exact fit;  
  
Improving the biological activity of materials. Clinical trial results have shown that PA implants promote a  
3. progressive shift of load to the new bone creating micro-motion and thereby avoiding bone atrophy due to ‘stress shielding’;
4. Reducing the chance of post-operative infection;
5. Stimulate bone tissues to facilitate effective biological integration, benefitting the regeneration of bone;
6. Ease of post-operative care i.e. no distortion during x-ray imaging;
7. Simple and cost-effective to manufacture.

Our products are designed to replace the traditional internal fixation device made of stainless steel and titanium and overcome the limitations of previous generations of products such as PLA and PLLA. Our laboratory statistics show that our PA products have a higher mechanical strength, last longer in degradation ratio and are more evenly absorbed from outer layer inwards as compared with similar materials such as PLA and PLLA. Thus PA allows increased restoration time for bone healing and re-growth. The Company’s polymer orthopaedic internal fixation screws received approval from the China Food and Drug Administration (“CFDA”) in April 2018.

### **CFDA Application Process and Approval for PA Screws**

The Company first submitted its application for PA Screws to the CFDA in 2008. The application has been withheld by the CFDA pending additional clinical trial cases. This is due to the amended CFDA regulations, which unlike previous regulations require the applicant to specify the position on the body where the clinical trial is carried out. Our amended CFDA application has specified the ankle fracture as the body part of our clinical trial. This is because bones around this part carry most of the body weight.

Due to the uniqueness of our material, there were no established CFDA Product Standards that we could follow during our application process for our PA Screws. To establish our own Product Standards, the Company had been carrying out extra tests. The Company submitted its Product Standards and supplementary reports to the CFDA in 2014. In



December 2016, the Company received a notice from the CFDA requesting supplementary report as part of the review process. The Company completed the supplementary report and submitted it to the CFDA in June 2017.

In April 2018, the Company's application for its PA Screws was approved by the CFDA in China (Medical Device Certification Number: 20183460133).

### **Process of Human Trials**

As of January 31, 2019, for medical study and comparison purpose, the Company has completed a total of 83 successful clinical human trial cases, including 71 cases on ankle fractures and 57 successful PA Binding Wire trial cases. We have been conducting human trials at the 6 state level hospitals recognized by CFDA for clinical trials in different cities throughout China; including Nanchang, Changsha, Luoyang, Nanning and Tianjin. The cities and provinces where our clinical trial hospitals are based will be the initial target regions on our marketing plan. These regions are both densely populated and have experienced high or above medium economic growth. The clinical trials for the Company's PA Screws have been completed with 100 percent success rate. Having gained CFDA approval for PA Screws, the Company is planning to start clinical trials on series of orthopaedic products the Company has developed using the same unique biomaterial.

## **Government Regulation**

Medical implant devices/products manufactured or marketed by the Company in China are subject to extensive regulations by the CFDA. Pursuant to the related laws and acts, as amended, and the regulations promulgated there under (the “CFDA Regulations”), the CFDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices. The CFDA also has the authority to request repair, replacement, or refund of the cost of any device manufactured or distributed by the Company.

Under the CFDA Regulations, medical devices are classified into three classes (class I, II or III), the basis of the controls deemed necessary by the CFDA to reasonably assure their safety and efficacy. Under the CFDA’s regulations, class I devices are subject to general controls (for example, labeling and adherence to Good Manufacturing Practices (“GMP”) requirements) and class II devices are subject to general and special controls. Generally, class III devices are those which must receive premarket approval by the CFDA to ensure their safety and efficacy (for example, life-sustaining, life-supporting and certain implantable devices, or new devices which have not been found substantially equivalent to legally marketed class I or class II devices). The Company is classified as a manufacturer of class III medical devices. Current CFDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

Before a new device can be introduced into the market in China, the manufacturer generally must obtain CFDA marketing clearance through clinical trials. Since the Company is classified as a manufacturer of Class III medical devices, the Company must carry out all clinical trials in pre-selected CFDA approved hospitals. The Company has one class III product and one class II product that have been approved by the CFDA.

Manufacturers of medical devices for marketing in China are required to adhere to GMP requirements. Enforcement of GMP requirements has increased significantly in the last several years and the CFDA has publicly stated that compliance will be more strictly scrutinized. Manufacturers of Class II and III medical devices must go through the process of examination and approval by the CFDA or authorized local CFDA’s for obtaining the medical device manufacturing license. The Company’s facilities in Shenzhen meets GMP standard and the Company’s CFDA manufacturing license is in good order.

## **Results of Operations**

The “Results of Operations” discussed in this section merely reflect the information and results of the Company for the period from September 25, 2002 (Shenzhen Changhua’s date of inception) to January 31, 2019 and 2018.

## Revenues

The Company received market permits for one class III product and one class II product in China in 2018 and is in its early marketing stage. The Company does not have any revenue and is expecting its first revenue from sales of its product in 2019. The management team is continuously looking for fundraising possibilities for product improvement, machinery upgrades, facility expansions, continuous research and development, and sales and marketing.

Our facility is located in Shenzhen China, which is built to meet the GMP standards. Our facility covers about 865 square meters, which includes the combined facilities of offices, laboratories, and workshops. There is one production line for the PA Screw and another production line for the PA Binding Wire. The annual production capabilities of each production line are 100,000 pieces for PA Screw, and 240,000 packs for the PA Binding Wires. Both production lines, at their maximum production capacity, are capable of generating approximately \$32,000,000 in annual revenue.

Estimate current production lines in full capacity

	Output Quantity (Max.)		Price at ex-factory (\$)	Total Turnover (\$)
PA Screw	100,000	(piece)	200	20,000,000
PA Binding Wire	240,000	(pack)	50	12,000,000
			<b>Total:</b>	32,000,000

### China's Marketing Analysis:

We have established long term relationships with many hospitals and national distributors in China. Ms. Hui Wang, the Company's CEO, has over 25 years' sales experience in medical distribution. She will be in charge of our sales programs. Professor Shangli Liu, our chief medical advisor, is one of the highest ranked orthopedic doctors in China as well as being highly renowned in the rest of the world. He will assist the Company in nationwide product promotion and joint projects with associated academic institutions and medical schools.

During product development and clinical trial stages, we developed close relationships with many major national hospitals. We expect these relationships to boost our revenue generation following CFDA final approval.

China's market for PA devices depends on 3 major conditions:

- Patients
- Advanced technology level
- Performance and price of the materials

The demand for internal fixation medical devices has rapidly increased during the last decade. According to China Health Care Year Book 2013, the total revenue of Chinese orthopaedic hospitals in 2013 was US\$1.28 billion with over 11.5 million patients. From 2009 to 2013, the market size of China's orthopaedic devices has grown from US\$1.1 billion to US\$1.92 billion, and it is estimated to reach US\$4 billion in 2020. China has overtaken Japan as the second largest market in the world. The Chinese market size for trauma treatment implant devices such as our PA Screw and PA Wire was US\$1.88 billion in 2013 and US\$2.12 billion in 2014 with a growth rate of 12.7%, it is estimated to grow to US\$3.02 billion in 2017 and reach US\$3.17 billion in 2018 with a growth rate of 11.6%<sup>9</sup>. (Source: Shenwan Hongyuan Securities research report).

The Company has advantages and more opportunities over other competitors due to:

- We are the only company received approval for our unique PA biomaterial by CFDA in China.
- No other similar patent registrations in China.
- We are the only company qualified and permitted to perform PA clinical trials by CFDA to the best of our knowledge.
- We have a timing advantage over other companies in China which would have to go through the preclinical testing for the CFDA permit on clinical trials.
- Under existing regulations by CFDA, it will take at least 3-5 years for clinical trials of new materials.

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*Number of Hospitals at the end of November 2018 Statistic and Census report by the National Health and Family Planning Commission of the People's Republic of China.*

Statistic and Census report by National Health and Family Planning Commission of the People's Republic of China (November 2018)

	November 2018	November 2017	Increase / (Decrease)
Total No. of Hospitals	32,476	30,294	2,182
Public Hospital	12,072	12,181	(109)
Private Hospital	20,404	18,113	2,291
<b>Hospital Rating</b>			
AAA	2,498	2,311	187
AA	8,806	8,285	521
A	10,477	9,632	845

In general, technological advancements and the marketing potential within Asia are the biggest factors in driving significant growth within the global orthopedic devices market. Another major factor that positively influences this market is the growing number of aging baby boomers with active lifestyles. This sector represents a large portion of the total population.

## Research and Development

The Company has developed five proprietary polymer fixation implant product lines, including screws, pins, tacks, rods and binding wires, which provide an alternative to metal implants and overcome the limitations of first generation polymer fixation devices. The Company's product range will ultimately cover the full gamut of components featuring PA macromolecule polymer materials for implantation, including human orthopaedic and dental applications, as well as veterinary applications. We expect research and development expenses to grow as we continue to invest in basic and advanced research, clinical trials, product development and in our intellectual property.

Although there are substantial research and development (R&D) activities within the Company and, the Company regards R&D activity as the key to maintain its technological advantage and innovation, there can be no assurance that the Company will be able to obtain any further clearances or approvals, if required, to market its products for their intended uses on a timely basis, if at all. Moreover, regulatory approvals, if granted, may include significant limitations on the indicated uses for which a product may be marketed. Delays in the receipt of or the failure to obtain such clearances or approvals, the need for additional clearances or approvals, the loss of previously received clearances or approvals, unfavorable limitations or conditions of approval, or the failure to comply with existing or

future regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

### **Marketing Strategy**

The Company has been conducting Pre-Market Research before its PA Screws application was approved by the CFDA in April 2018. The research is intended to estimate the potential market success of the company's products that can be expected. The research also beyond the Company's initial market - China, and covers international markets. Based on the results of our Pre-Market Research and the positive feedbacks we have received from trade shows and industrial conferences, it is the Company's intention to apply for additional international regulatory approvals in due course.

The Company will market its products through a hybrid sales force comprised of a managed network of independent regional distributors/sales agents (80%) and direct sales representatives (20%) in China.

There are two ways the Company will generate revenue, 1) through our nationwide and regional distributors and 2) through our direct sales channels.

The Company is currently working to have its products registered on multiple provincial Group Purchasing Organization (GPO) platforms. A few distributors have made deposit payment and the Company will start production in due course.

### **Finance Costs**

As of January 31, 2019 and October 31, 2018, a stockholder and four related parties had loaned a total of \$5,475,220 and \$5,044,379 respectively to the Company as unsecured loans repayable on demand and interest is charged at 7% per annum on the amount due. Total interest expenses on advances from a stockholder and the related parties accrued for the three months ended January 31, 2019 and 2018 were \$75,507 and \$67,546 respectively.

As of January 31, 2019 and October 31, 2018, the Company owed \$277,628 and \$273,874 respectively to the directors for advances made on an unsecured basis, repayable on demand. Total imputed interest expenses on advances from directors, calculated at 5% per annum, recorded as additional paid-in capital amounted to \$3,148 and \$3,844 for the three months ended January 31, 2019 and 2018 respectively.

### **Net Loss**

The net loss attributable to common stockholders for the three months ended January 31, 2019 and 2018 were \$252,523 and \$222,543 respectively. We do not have any revenue from inception to January 31, 2019 but have to incur operating expenses for the upkeep of the Company and the clinical trials.

### **Liquidity and Capital Resources**



We had a working capital deficit of \$6,207,713 and \$5,721,907 as of January 31, 2019 and October 31, 2018 respectively. Our working capital deficit is due to the fact that we received the CFDA approval for one product in April 2018 and we are in the process to produce, market and sell our product in China. We had no revenues during the period and that our sole source of financing is loans from our related parties and stockholders. Meanwhile, we have been upgrading our facilities and continuing R&D works.

## **Cash Flows**

### *Net Cash Used in Operating Activities*

Net cash used in operating activities was \$199,767 and \$228,331 in the three months ended January 31, 2019 and 2018 respectively. This amount was attributable primarily to the net loss after adjustment for non-cash items, such as depreciation, loss on disposal of property and equipment, imputed interest on advances from directors, and others like charges in other receivables and prepaid expenses and other payables and accrued expenses.

*Net Cash Used in Investing Activities*

We recorded \$25,043 net cash used and \$4,457 net cash from in investing activities in the three months ended January 31, 2019 and 2018 respectively. This amount reflected purchases of property and equipment, primarily for research and development to our facilities.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities in the three months ended January 31, 2019 and 2018 was \$234,622 and \$243,455 respectively, which represented advances from a stockholder, directors and related parties, loan repayment to directors and advances to a related company.

**Operating Capital and Capital Expenditure Requirements**

Our ability to continue as a going concern and support the commercialization of current products is dependent upon our ability to market our product while obtaining additional financing in the near term. We anticipate that such funding will be in the form of equity financing from sales of our common stock. However, there is no assurance that we will be able to raise sufficient funding from the sale of our common stock to fund our business plan should we decide to proceed. We anticipate continuing to rely on advances from our related parties and stockholders in order to continue to fund our business operations.

We believe that our existing cash, cash equivalents at January 31, 2019, will be insufficient to meet our cash needs. Our minimum cash requirement for the next 12 months is projected to be \$750,000. This amount may increase if we decide to start clinical trials on new products. Once we start production and marketing of our PA Screws, our revenue will cover our basic expenditures. Otherwise, we will continue to rely on external investments and shareholder's loans to meet our cash needs. The management is actively pursuing additional funding and strategic partners, which will enable the Company to implement our business plan, business strategy, to continue research and development, clinical trials or further development that may arise.

We intend to spend more to support the commercialization of current products and on research and development activities, including new products development, regulatory and compliance, clinical studies, and the enhancement and protection of our intellectual property portfolio.

## OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to our investors.

## CRITICAL ACCOUNTING POLICIES

The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including but not limited to those related to income taxes and impairment of long-lived assets. We base our estimates on historical experience and on various other assumptions and factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Based on our ongoing review, we plan to adjust to our judgments and estimates where facts and circumstances dictate. Actual results could differ from our estimates.

We believe the following critical accounting policies are important to the portrayal of our financial condition and results and require our management's most difficult, subjective or complex judgments, often because of the need to make estimates about the effect of matters that are inherently uncertain.

#### 1. Property and equipment

Property and equipment are stated at cost, less accumulated depreciation. Expenditures for additions, major renewals and betterments are capitalized and expenditures for maintenance and repairs are charged to expense as incurred.

Depreciation is provided on a straight-line basis, less estimated residual value over the assets estimated useful lives. The estimated useful lives of the assets are 5 years.

#### 2. Long-lived assets

In accordance with FASB Codification Topic 360 (ASC Topic 360), "Accounting for the impairment or disposal of Long-Lived Assets", long-lived assets and certain identifiable intangible assets held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. For purposes of evaluating the recoverability of long-lived assets, the recoverability test is performed using undiscounted net cash flows related to the long-lived assets. The Company reviews long-lived assets to determine that carrying values are not impaired.

#### 3. Fair value of financial instruments

FASB Codification Topic 825 (ASC Topic 825), "Disclosure About Fair Value of Financial Instruments," requires certain disclosures regarding the fair value of financial instruments. The carrying amounts of other receivables and prepaid expenses, other payables and accrued liabilities and due to a stockholder, directors and related parties approximate their fair values because of the short-term nature of the instruments. The management of the Company is of the opinion that the Company is not exposed to significant interest or credit risks arising from these financial statements.

#### 4. Income taxes

The Company accounts for income taxes under The Financial Accounting Standards Board (FASB) Codification Topic 740-10-25 ("ASC 740-10-25"). Under ASC 740-10-25, deferred tax assets and liabilities are recognized for the

future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740-10-25, the effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period included the enactment date.

#### 5. Research and Development

Research and development costs related to both present and future products are expensed as incurred.

## 6. Foreign currency translation

The reporting currency of the company's financial statements is the US dollar. The financial statements of the Company's subsidiary denominated in currencies other than the US dollar are translated into US dollars using the closing rate method. The balance sheet items are translated into US dollars using the exchange rates at the respective balance sheet dates. The capital and various reserves are translated at historical exchange rates prevailing at the time of the transactions while income and expenses items are translated at the average exchange rate for the year. All exchange differences are recorded within equity.

## RECENT ACCOUNTING PRONOUNCEMENTS

There has been no newly effective accounting pronouncement that has significance, or potential significance, to our consolidated financial statements.

### Accounting Pronouncements Not Yet Effective

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which modifies lease accounting for lessees to increase transparency and comparability by recording lease assets and liabilities for operating leases and disclosing key information about leasing arrangements. The new standard, as amended by ASU 2018-01, ASU 2018-10, ASU 2018-11 and ASU 2019-01, is effective for annual periods beginning after December 15, 2018 on a modified retrospective basis. The Company will adopt ASU 2016-02 in its first quarter of the year ending October 31 2020. The Company expects its leases designated as operating leases in Note 6, "Commitments and Contingencies," will be reported on the consolidated balance sheets upon adoption. However, the ultimate impact of adopting ASU 2016-02 will depend on the lease terms as of the adoption date.

The Company has reviewed all other recently issued, but not yet effective, accounting pronouncements and do not believe the future adoptions of any such pronouncements may be expected to cause a material impact on the financial condition or the results of operations.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. Our disclosure controls and procedures are designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of January 31, 2019 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of January 31, 2019.

#### **Changes in Internal Control**

During the most recently completed fiscal quarter, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, its internal control over financial reporting.

**PART II – OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

Currently we are not involved in any pending litigation or legal proceeding.

**ITEM 1A. RISK FACTORS**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

**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**



None.

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## ITEM 6. EXHIBITS

The following documents are filed as a part of this report or are incorporated by reference to previous filings, if so indicated:

Exhibit No. Description

3.1 Articles of Incorporation (1)

3.2 Bylaws (1)

31.1 Section 302 Certification of Chief Executive Officer\*

31.2 Section 302 Certification of Chief Financial Officer \*

32.1 Section 906 Certification of Chief Executive Officer \*

32.2 Section 906 Certification of Chief Financial Officer \*

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

\*filed herewith

(1) Incorporated by reference to the Form SB-2 registration statement filed on January 16, 2007.

**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.

Date: April 1, 2019 By:

**ADVANCED BIOMEDICAL TECHNOLOGIES, INC.**

By: */s/ Chi Ming Yu*

Chi Ming Yu, President and Director

(Principal Executive Officer)

By: */s/ Hui Wang*

Hui Wang, Director and Chief Executive Officer

(Controller)

By: */s/ Kai Gui*

Kai Gui, Director, Secretary and Chief Financial Officer

(Principal Financial Officer)

