New Venturetec
Semi-Annual Report
March 31, 2019

Contents

Disclaimer

New Venturetec Ltd. is an investment company investing in venture portfolio companies which are in their early development stage, with no history of revenues, earnings or significant operations, and are subject to all of the risks inherent in the venture business. Currently, New Venturetec Ltd. holds two investments in public companies. No investment in New Venturetec Ltd. shares should be made by any person who is not in a position to bear the economic risk including the possibility of the loss of the entire amount of such investment. The risk is 100%.

Any forward looking statements or projections made by the Company or its portfolio companies, including those made in this report, are based on management's expectations at the time they are made, and are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Specifically, discussions of possible future growth and development in revenue and customers are forward looking in nature, and actual results could differ materially from current expectations. Each of the portfolio companies' future results may be impacted by factors such as technological changes, market acceptance of the companies' services and products, ability to grow its customer base, and competitive market pressures, among other things.

The shares of New Venturetec Ltd. are listed on the SIX Swiss Exchange. The price per share is based on supply and demand on the market. Further, the trading of New Venturetec Ltd. shares may be rather illiquid. New Venturetec Ltd. does not make a market in its shares and the Company has no agreement with any market maker. No assurance can be given that any operational development of the Company or its portfolio is not affecting the price of the New Venturetec Ltd. shares on the market.

Some of the investees may be in a development stage, disclosing accumulated deficits and little or no revenues. Their ability to continue as a going concern may depend on additional funding. Companies which are in the need of cash often face unfavourable financing terms to existing shareholders – in our case New Venturetec Ltd. – which basically means heavy dilution and unfavourable liquidation preferences in case of a trade sale. This is only if the company is able to attract investments in the first place for which no assurance can be given that this may occur. These investments offer the opportunity of significant capital gains, but involve a high degree of business and financial risks that can result in substantial losses, including the risk of a total unrecoverability of an investment. The financial risk management objectives and policy of New Venturetec Ltd. are to minimize dilution by structuring the initial investment accordingly. Other protective measures such as liquidation preferences are also part of the Company's policy. However, the operational risk remains. Furthermore, the Company does not hedge any foreign currencies or interest rate risk exposure.

New Venturetec Ltd. Shareholders should be aware of the risks which could result in a loss of 100% of the investment. This is a real possibility. Any investor should only invest in New Venturetec Ltd. if he can afford the complete loss of the investment without having to change his lifestyle.

Risks

The risk of venture capital investments is 100%

As briefly outlined earlier, New Venturetec Ltd. offers the opportunity for capital gains. However, no assurance can be given that such returns can be realized. The risk of venture capital investments is 100%. In order for the Company to be successful in investing in start-up and emerging companies, it must identify potentially profitable enterprises at an early stage in their development, a process which is very difficult even for people with considerable experience in the venture capital field. Furthermore, the Company is competing for investment opportunities with a number of other venture capital firms. The Company may also invest in businesses which are not start-up or emerging companies, but which are for various reasons seeking to raise additional capital without making a public offering of securities. These reasons can include adverse conditions in the public securities markets, or a record of earnings and/or growth, which is less than adequate for a successful public offering of securities.

Lack of liquidity of investments

Investments will usually consist of securities that are subject to restrictions on resale as they are acquired from companies in private placement transactions. Neither the Company nor any investors, to whom the Company distributes restricted securities, will be able to sell such restricted securities to the public unless the sale is registered under applicable Federal and State securities laws, or unless an exemption from such registration is available. In connection with any particular portfolio investment, the Company may negotiate for rights to require registration under the Act. No assurance can be given, however, that the Company will be successful in such negotiations or that registration will provide adequate means of liquidating such investment.

Currently, New Venturetec Ltd. holds two investments in public companies.

Management, technological risks

The quality of the management of venture companies included in the portfolio of the Company is crucial for the success of the investments of the Company. Although the Company will use its expertise and experience in assessing the quality of the management, the Company has to fully rely on the management of the companies contained in the Company's investment portfolio.

Furthermore, no assurance can be given that the management will be successful in handling the technological risks, which are inherent in projects of startup companies. Research might not lead to satisfactory results and technological improvements or changes by competitors might endanger the successful launch of a product or service.

Currency risks

The Net Asset Value per share is published in US Dollars. The Company's investments are usually made in US Dollars. Any investment in other currencies than the US Dollar might lead to positive or negative impacts on the Company's performance in its annual financial statements, including its income statement. The Company's IFRS financial statements are presented in US Dollar. The fluctuation of foreign currencies could substantially impact the Net Asset Value per share.

Since the Company's shares are listed in Swiss francs, fluctuation in exchange rates between the Swiss franc and the US Dollar could also materially impact the price of the Company's shares. Nevertheless, the Company does not hedge against these currency risks.

Political, regulatory risks

The value of the Company's assets may be affected by uncertainties such as international political developments, transfer risks, changes in government policies, taxation, restriction on foreign investment and other developments in the laws and regulations of the countries in which the Company's assets are invested. This is especially the case in the biotechnology and communications sectors, where successful launches of products are dependent on government approval (such as FDA for biotechnology and FCC for telecommunications firms).

Market risks

The markets and individual investment vehicles in which the Company will primarily invest may prove to be highly volatile from time to time as a result of market specific risk. This may be, for example, due to a sudden change in underlying economic factors as well as changes in government policies on taxation or changes in legislation relating to the level of foreign ownership in companies.

The company's share price

Considerable price fluctuations in the shares may arise due to the general position of the investment sector, the economy as a whole and the financial markets. Such price fluctuations could have a positive and negative effect on the share price regardless of the Company's financial condition and results of operations.

Patent risks and proprietary rights

The success of the investments will depend largely on the ability to obtain patents on products to protect trade secrets and to operate without infringing the proprietary rights of others.

Legal standards regarding the scope of claims and the validity of patents, e.g. in the biotechnology market, are uncertain and evolving. There can be no assurance that the underlying firms' patents will provide them with significant competitive advantages, or that challenges will not be instituted against the validity or enforceability of any patent owned by the firms. The cost of litigation to uphold the validity and prevent infringement of a patent is substantial.

Financial reporting

The accounting, auditing, financial and disclosure requirements and reporting standards of the Company are those defined in the International Financial Reporting Standards of the International Accounting Standards Board. The net asset value is based on estimates of the Company. Investors should recognize that the monthly calculation is based on indicative values and may therefore contain only limited information on the real value of the net assets of the Company. The difficulties involved in calculating the net asset value are discussed further in note 6.1 on page 15.

Investment advisor

The Company is advised by Madison Investment Advisory, Inc., owned by Peter Friedli. The Company uses the ability of the investment advisor to evaluate investment opportunities and to further develop the Company's investments. The investment advisor advises the Board on all investment decisions for the Company as well as the net asset value computation. The Board of Directors is responsible for ensuring the Investment Policy set by the Company are strictly followed. It should be realized that Peter Friedli is the key person for both the investment advisor and the Board of Directors and that between him and the Company conflicts of interests may arise.

Liquidity risk

New Venturetec Ltd. operates on tight liquidity and has to generate cash to cover its operational costs and interest. Further, the Company has liabilities outstanding in the amount of USD 20,518,774 as per March 31, 2019. New Venturetec Ltd. does not have any operational income and consequently the only way to generate liquidity is through the sale of assets or funding through additional debt or equity.

Liquidity of Venturetec's investment in Osiris Therapeutics

New Venturetec Ltd. directly owns 4,103,301 shares of Osiris Therapeutics, which represents approx. 12% of the outstanding shares of Osiris Therapeutics. Based on this ownership, New Venturetec Ltd. is a reporting person in respect of Osiris Therapeutics and is subject to reporting requirements of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). New Venturetec Ltd. has reported its transactions and holdings of Osiris Therapeutics with the United States Securities and Exchange Commission (SEC) through the filing of Forms 3 and 4, consistently since first becoming a reporting person following the IPO of Osiris Therapeutics.

The sale by New Venturetec Ltd. of shares of Osiris Therapeutics common stock requires either registration under the Securities Act of 1933, as amended (the "Securities Act"), or that the sale be exempt from registration. Rule 144 under the Securities Act provides a safe harbor from registration for sales by a person other than an issuer, underwriter or dealer. Compliance with Rule 144 requires compliance with various restrictions set forth in the rule, including limitations on the number of shares sold in a given period and the manner in which sales may be completed. For sales by an affiliate of an issuer, which New Venturetec Ltd. is presumed to be, Rule 144 provides that the volume of securities sold during any preceding three-month period may not exceed the greatest of certain limitations.

Rule 144 also requires, in the case of affiliate sales, that a Form 144 be filed with the SEC in advance of the sale. The sale must then take place within 90 days after the filing of the Form 144. If and when a sale transaction occurs, the sale must be reported to the SEC by the filing of a Form 4, within two days.

In addition, as a greater than 10% shareholder, New Venturetec Ltd. is further limited as to when it can engage in purchasing or selling shares of Osiris Therapeutics. New Venturetec Ltd. is subject to Osiris' Trading Window and must clear all purchase and/or sales transactions in the company's common stock with either the President & CEO or the Chief Financial Officer. Osiris' Trading Window usually closes 15-days prior to the end of each fiscal quarter and then reopens on the third Trading Day after the financial results for the quarter are published, which typically is 35 – 45 days after the fiscal quarter end. The Trading Window may also close during other times at the discretion of the company.

On April 17, 2019, Osiris Therapeutics, Inc. announced that it has completed the previously announced sale of Osiris to Smith & Nephew plc ("Smith & Nephew") through the consummation of a merger of Osiris with and into an indirect wholly-owned subsidiary of Smith & Nephew (the "Subsidiary") without a vote of the Osiris stockholders in accordance with Section 3-106.1 of the Maryland General Corporation Law. More than a majority of the outstanding shares of Osiris common stock were tendered in the tender offer. New Venturetec Ltd. did not tender its shares, which have been converted into the right to receive $19.00 per share in cash in the second-step merger.

Risks of Osiris Therapeutics

Extracts from Osiris Therapeutics 10k Reporting 2018 regarding specific risk factors of the company shall be studied on Annex I on page 30.

New Venturetec Ltd., Zug

Interim Financial Statements

October 1, 2018 to March 31, 2019

Condensed Interim Balance Sheet

	Note	March 31, 2019 (unaudited) USD	September 30, 2018 (audited) USD
Assets			
Cash and cash equivalents		74,308	956,756
Other accounts receivable		11,166	6,383
Current assets		**85,474**	**963,139**
Venture capital investments	7	83,274,719	52,906,641
Non-current assets		**83,274,719**	**52,906,641**
Total assets		**83,360,193**	**53,869,780**
Liabilities and equity			
Accrued advisory fees		134,869	77,280
Other accrued expenses		117,519	163,208
Convertible notes	10/14.3	12,688,780	12,278,526
Loans payable to related parties	9/14.3	7,577,606	6,401,723
Current liabilities		**20,518,774**	**18,920,737**
Convertible notes	10	0	1,053,358
Loans payable to related parties	9/14.3	0	991,219
Non-current liabilities		**0**	**2,044,577**
Total liabilities		**20,518,774**	**20,965,314**
Share capital	12	20,785,350	20,785,350
Additional paid-in capital	12	28,784,665	28,784,665
Translation reserve		977,151	1,397,499
Conversion options / own equity instruments		1,018,322	741,767
Retained earnings / (accumulated losses)		11,275,931	(18,804,815)
Equity attributable to shareholders of New Venturetec		**62,841,419**	**32,904,466**
Total liabilities and equity		**83,360,193**	**53,869,780**
Number of shares outstanding		5,000,000	5,000,000
Net asset value per share		**12.57**	**6.58**

Condensed Interim Statement of Comprehensive Income

	Note	Six months ended March 31, 2019 (unaudited) USD	Six months ended March 31, 2018 (unaudited) USD
Income			
Gains on venture capital investments	7.2	33,009,847	0
Profit on investment in non-consolidated subsidiary at fair value through profit or loss	8.1	0	15,376,413
Net foreign exchange gain		7,520	0
		33,017,367	**15,376,413**
Expenses			
Loss on venture capital investments	7.2	(1,944,738)	0
Advisory fees	14.1	(218,730)	0
Interest on loans from related parties	14.3/14.4	(1,137,692)	(877,940)
Interest on loans from third parties		(59,834)	(64,821)
Interest on loans and current accounts with non-consolidated subsidiary		0	(16,620)
Administration cost		(158,022)	(235,057)
Net foreign exchange loss		0	(173)
		(3,519,016)	**(1,194,611)**
Profit before tax		**29,498,351**	**14,181,802**
Income tax		0	0
Profit for the period attributable to shareholders		**29,498,351**	**14,181,802**
Other comprehensive income			
Items that are or may be reclassified to profit or loss			
Translation adjustment		(420,348)	285,734
Total items that are or may be reclassified to profit or loss		**(420,348)**	**285,734**
Other comprehensive income for the year		**(420,348)**	**285,734**
Total comprehensive income for the period attributable to shareholders		**29,078,003**	**14,467,536**
Weighted average number of shares outstanding during the year (basic)		5,000,000	5,000,000
Earnings per share (basic)	15	**5.90**	**2.84**
Weighted average number of shares outstanding during the year (diluted)		6,381,578	6,036,883
Earnings per share (diluted)	15	**4.74**	**2.39**

Condensed Interim Statement of Changes in Equity for the six months ended March 31, 2019 and 2018

	Share capital USD	Additional paid-in capital USD	Translation reserve USD	Conversion options / own equity instruments (note 10/11) USD	(Accumulated losses) / Retained earnings USD	Total equity attributable to shareholders of New Venturetec USD
Balance as of 01.10.2017	**20,785,350**	**28,784,665**	**1,634,566**	**168,451**	**(45,856,868)**	**5,516,164**
Translation adjustment	0	0	285,734	0	0	285,734
Total other comprehensive income	**0**	**0**	**285,734**	**0**	**0**	**285,734**
Profit for the period	0	0	0	0	14,181,802	14,181,802
Total comprehensive income	**0**	**0**	**285,734**	**0**	**14,181,802**	**14,467,536**
Forfeiture of conversion options on convertible bonds	0	0	0	(168,451)	168,451	0
Issue of convertible notes / conversion option	0	0	0	159,372	0	159,372
Shareholders' contribution	0	0	0	0	331,581 [1)]	331,581
Transactions with owners of the Company	**0**	**0**	**0**	**(9,079)**	**500,032**	**490,953**
Balance as of 31.03.2018	**20,785,350**	**28,784,665**	**1,920,300**	**159,372**	**(31,175,034)**	**20,474,653**
Balance as of 01.10.2018	**20,785,350**	**28,784,665**	**1,397,499**	**741,767**	**(18,804,815)**	**32,904,466**
Translation adjustment	0	0	(420,348)	0	0	(420,348)
Total other comprehensive income	**0**	**0**	**(420,348)**	**0**	**0**	**(420,348)**
Profit for the period	0	0	0	0	29,498,351	29,498,351
Total comprehensive income	**0**	**0**	**(420,348)**	**0**	**29,498,351**	**29,078,003**
Forfeiture of conversion options on convertible bonds	0	0	0	(582,395)	582,395	0
Issue of convertible notes / conversion option	0	0	0	858,950	0	858,950
Transactions with owners of the Company	**0**	**0**	**0**	**276,555**	**582,395**	**858,950**
Balance as of 31.03.2019	**20,785,350**	**28,784,665**	**977,151**	**1,018,322**	**11,275,931**	**62,841,419**

[1] See Note 14.3 and Note 14.5

Condensed Interim Cash Flow Statement [1)]

		Six months ended March 31, 2019 (unaudited) USD	Six months ended March 31, 2018 (unaudited) USD
Advisory fees paid		(161,141)	0
Payments for general and administrative expenses		(206,287)	(590)
Payment received from non-consolidated subsidiary		0	1,653,576
Cash provided by operating activities		**(367,428)**	**1,652,986**
Increase of loans payable to related parties	9	0	2,211,239
Redemption of convertible bonds	11	0	(3,178,980)
Interest paid			
- for loans payable to related parties	9	(152,349)	0
- for convertible notes	10	(357,154)	0
- for convertible bonds	11	0	(622,365)
Cash used in financing activities		**(509,503)**	**(1,590,106)**
Net change in cash and cash equivalents		**(876,931)**	**62,880**
Cash and cash equivalents at beginning of year		956,756	21,600
Exchange effect on cash and cash equivalents		(5,517)	7,800
Cash and cash equivalents at end of period		**74,308**	**92,280**

[1] For significant non-cash transactions refer to Note 13.

Notes to the condensed financial statements for the six months ended March 31, 2019

Basis of the financial statements

1. Principal activities

New Venturetec Ltd., Zug ("the Company") was formed on July 16, 1997 and incorporated on August 8, 1997 for the purpose of direct and indirect investments in Swiss and foreign companies, especially in high risk venture capital companies in the industries of Biotechnology and Technology. The Company is domiciled in Zug.

2. Statement of compliance

The condensed interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting and comply with Swiss law and the special provisions for investment companies according to the Listing Rules and the Directive of Financial Reporting of the SIX Swiss Exchange.

The principles of accounting applied for the condensed interim financial statements as of March 31, 2019 generally correspond to those of the annual financial statements as of September 30, 2018.

The condensed interim financial statements do not include all the information required for a complete set of IFRS financial statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements as at and for the year ended September 30, 2018.

3. Judgement involved in the application of accounting policies, management assumptions and estimates

The preparation of financial statements in accordance with IFRS requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Classification as an investment entity

Management concluded that New Venturetec Ltd. meets the definition of an investment entity, as the following conditions are met:

- New Venturetec Ltd. holds multiple investments;
- New Venturetec Ltd.'s business purpose is to invest in securities of any form of Swiss or foreign corporations taking advantage of particular corporate circumstances with the goal to achieve returns from capital appreciation and investment income;
- The performance of these investments is measured and evaluated on a fair value basis.

Notes to the condensed financial statements for the six months ended March 31, 2019

4. Basis of presentation

The financial statements are those of New Venturetec Ltd. The financial statements are presented in USD. They are prepared on a fair value basis for venture capital investments. Other financial assets and liabilities are stated at amortized cost.

4.1. New and revised standards adopted

As of October 1, 2018, the Company adopted the following new and revised IFRS standards and IFRS interpretations:

Revisions and amendments of Standards and Interpretations	Effective date
IFRS 9, Financial instruments	January 1, 2018
IFRS 15, Revenue from contracts with customers	January 1, 2018

The adoption of the above amendments did not have an impact on the financial statements.

New Venturetec Ltd. has initially adopted IFRS 9, Financial Instruments effective as of October 1, 2018. IFRS 9 replaces IAS 39 Financial Instruments: Recognition and Measurements.

IFRS 9 includes revised guidance on the recognition, classification and measurement of financial assets and financial liabilities and replaces the incurred loss model in IAS 39 with an expected credit loss model ("ECL"). The new impairment model applies to financial assets measured at amortized cost and debt investments at fair value through other comprehensive income, but not to investments in equity instruments.

The transition from IAS 39 to IFRS 9 as of October 1, 2018 did not have a material impact on the measurement of New Venturetec Ltd.'s financial assets and financial liabilities and did not have a material impact on its opening equity as of October 1, 2018 as financial assets in the scope of ECL (cash and cash equivalents) are of short-term nature and the major counterparty has investment grade credit rating.

From October 1, 2018, New Venturetec Ltd. classifies its financial assets in the following measurement categories:

- Those to be measured at fair value (either through other comprehensive income or through profit or loss); and
- those to be measured at amortized cost.

The classification depends on the business model for managing the financial assets and the contractual terms of the cash flows.

New Venturetec Ltd. has assessed which business models apply for the financial assets held.

The following table sets out the original measurement categories under IAS 39 and the new measurement categories under IFRS 9 for each item of New Venturetec Ltd.'s financial assets and financial liabilities as at October 1, 2018:

01.10.2018	Classification		Carrying amount	
	under IAS 39	under IFRS 9	under IAS 39 USD	under IFRS 9 USD
Cash and cash equivalents	Loans and receivables	Amortized cost	956,756	956,756
Venture capital investments	At fair value through profit or loss	At fair value through profit or loss	52,906,641	52,906,641
Total financial assets			**53,863,397**	**53,863,397**
Accrued advisory fees	Amortized cost	Amortized cost	77,280	77,280
Other accrued expenses	Amortized cost	Amortized cost	163,208	163,208
Loans payable to related parties	Amortized cost	Amortized cost	7,392,942	7,392,942
Convertible notes	Amortized cost	Amortized cost	13,331,884	13,331,884
Total financial liabilities			**20,965,314**	**20,965,314**

Cash and cash equivalents previously classified as loans and receivables under IAS 39 are now classified at amortized cost. No impairment is recognized, neither to the transition to IFRS 9 as of October 1, 2018 nor during the six months period ended March 31, 2019. The impairment balance as of March 31, 2019 is not material and therefore has not been recognized as financial assets in the scope of ECL are of short-term nature and the major counterparty has investment grade credit rating.

4. Basis of presentation (continued)

4.2. New standards and interpretations issued but not yet adopted

A number of new standards are effective for annual periods beginning after 1 January 2019 and earlier application is permitted; however, New Venturetec Ltd. has not early applied these new or amended standards in preparing these financial statements. Of those standards that are not yet effective, none is expected to have a material impact on New Venturetec Ltd.'s financial statements in the period of initial application.

5. Summary of significant accounting policies

5.1. Foreign currency translation

Transactions in foreign currencies are translated at the foreign exchange rate at the date of the transaction. Monetary assets and liabilities in foreign currencies are translated at the foreign exchange rate at the balance sheet date. Foreign exchange differences arising on translation are recognized in profit or loss.

The functional currency of New Venturetec Ltd. is CHF. Assets and liabilities of the Company are translated to the presentation currency (USD) at the foreign exchange rates at the balance sheet date. The revenues and expenses are translated to USD at average rates. Foreign exchange differences arising on this translation are recognized directly in other comprehensive income (equity) within the translation reserve.

Foreign exchange differences on cash and cash equivalents are presented separately in the cash flow statement.

5.2. Venture capital investments / Determination of fair value

The Company's investments relate to U.S. venture capital companies.

All venture capital investments are classified as financial assets at fair value through profit or loss. The venture capital investments are initially measured at fair value on the trade date, excluding transaction costs. Upon initial recognition attributable transaction costs are recognized in profit or loss when incurred. These investments are subsequently measured at fair value, with changes in the fair value recognized in profit or loss.

The venture capital investments are stated at fair value on an item by item basis, as determined by the Investment Advisor and approved by the Board of Directors. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date in the principal, or in its absence, the most advantageous market to which the Company has access at that date. Options and similar rights attached to the investments are also considered in determining fair value.

Currently, New Venturetec Ltd. holds two investments in public companies.

The basis for the fair valuation of investments in public companies is the following:

The fair value of public companies equals the closing bid price on the reporting date as reported by the exchange where the shares are quoted and traded. Estimated future selling costs are not deducted. The following aspects are excluded from the determination of fair value:

- Investments may be subject to lock-up agreements during a certain period.

The reliability of the fair value depends on whether one or more buyers would be willing to acquire the entire share held in the investee at the publicly listed price.

5. Summary of significant accounting policies (continued)

5.3. Cash and cash equivalents

Cash and cash equivalents include cash at banks, call money and fixed term deposits with a term of three months or less from the date of acquisition. They are stated at their amortized cost.

5.4. Other accounts receivable

Other accounts receivable results from VAT. Other accounts receivables are initially recognized at their fair values, subsequently, they are measured at amortized cost, which approximates fair value.

5.5. Loans payable

Interest-bearing borrowings are recognized initially at fair value, less any attributable transaction costs. Subsequent to initial recognition, interest-bearing borrowings are carried at amortized cost using the effective interest method.

5.6. Convertible notes

Compound financial instruments issued by the Company comprise convertible notes denominated in CHF that can be converted to ordinary shares at the option of the holder. The number of shares to be issued is fixed and does not vary with changes in fair value.

The liability component of compound financial instruments is initially recognized at the fair value of a similar liability that does not have an equity conversion option. The equity component is initially recognized at the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts.

Subsequent to initial recognition, the liability component of a compound financial instrument is measured at amortised cost using the effective interest method. The equity component of a compound financial instrument is not remeasured.

Interest related to the financial liability is recognized in profit or loss. On conversion, the financial liability is reclassified to equity and no gain or loss is recognized.

5.7. Income taxes

The Company is taxed as a holding company in the Canton of Zug. Income, including dividend income and capital gains from its investments, is exempt from taxation at the cantonal and communal level.

For Swiss federal tax purposes, income tax at an effective tax rate of 7.83% is levied. However, dividend income qualifies for the participation exemption if the related investment represents at least 10% of the other company's share capital or has a value of not less than CHF 1 million. The participation exemption is extended to capital gains on the sale of a substantial investment (i.e. at least 10%), which was held for a minimum holding period of one year and in case the sales price of the participation exceed its original acquisition cost. The result of the participation exemption pursuant to the aforementioned requirements is that dividend income and capital gains (except recovered depreciations) are almost fully exempt from taxation.

Deferred income taxes are recognized at the expected applicable tax rates on any temporary differences, both taxable and deductible, between the carrying amount and the tax base of assets and liabilities. In measuring the deferred tax assets or liabilities, the manner in which New Venuretec Ltd. expects, at the balance sheet date, to recover or settle the carrying amount of its assets and liabilities is taken into account.

Notes to the condensed financial statements for the six months ended March 31, 2019

Notes to the balance sheet

6. Financial instruments and fair value

6.1. Fair value information

Fair values are measured using the following fair value hierarchy that reflects the significance of the inputs used in making the measurements:

- Level 1: Quoted market price (unadjusted) in an active market for an identical instrument.
- Level 2: Valuation techniques based on observable inputs, either directly (i.e. as prices) or indirectly (i.e. derived from prices). This category includes instruments valued using: quoted market prices in active markets for similar instruments; quoted prices for identical or similar instruments in markets that are considered less than active; or other valuation techniques where all significant inputs are directly or indirectly observable from market data.
- Level 3: Valuation techniques using significant unobservable inputs. This category includes all instruments where the valuation technique includes inputs not based on observable data and the unobservable inputs have a significant effect on the instrument's valuation.

Fair values of financial assets and financial liabilities that are traded in active markets are based on quoted market prices or dealer price quotations.

For all other financial instruments, fair values are determined using valuation techniques.

Valuation techniques to estimate the fair values include net present value and discounted cash flow models, comparison to similar instruments for which market observable prices exist if applicable, Black-Scholes and polynomial option pricing models and other valuation models. Assumptions and inputs used in valuation techniques include risk-free and risk adjusted interest rates and other premia used in estimating discount rates. The objective of valuation techniques is to arrive at a fair value determination that reflects the price of the financial instrument at the reporting date that would have been determined by market participants acting at arm's length.

6 Financial instruments and fair value (continued)

6.2. Categories of financial instruments and fair value

The following table shows the carrying amounts and fair values of financial assets and financial liabilities, including their levels in the fair value hierarchy. It does not include fair value information for financial assets and financial liabilities not measured at fair value if the carrying amount is a reasonable approximation of fair value.

31.03.2019	Carrying amount	Fair value			
		Level 1	Level 2	Level 3	Total
	USD	USD	USD	USD	USD
Cash and cash equivalents	74,308				
Total financial asstes at amortized costs	**74,308**				
Venture capital investments	83,274,719	83,274,719	0	0	83,274,719
Total financial assets at fair value through profit or loss	**83,274,719**				
Accrued advisory fees	134,869				
Other accrued expenses	117,519				
Convertible notes	12,688,780	0	0	12,714,241	12,714,241
Loans payable to related parties	7,577,606	0	0	7,574,530	7,574,530
Total financial liabilities at amortized cost	**20,518,774**				

30.09.2018	Carrying amount	Fair value			
		Level 1	Level 2	Level 3	Total
	USD	USD	USD	USD	USD
Cash and cash equivalents	956,756				
Total financial assets at amortized costs	**956,756**				
Venture capital investments	52,906,641	52,906,641	0	0	52,906,641
Total financial assets at fair value through profit or loss	**52,906,641**				
Accrued advisory fees	77,280				
Other accrued expenses	163,208				
Convertible notes	13,331,884	0	0	13,341,425	13,341,425
Loans payable to related parties	7,392,942	0	0	7,400,924	7,400,924
Total financial liabilities at amortized cost	**20,965,314**				

Due to their short maturity, the carrying amounts of cash and cash equivalents, accrued advisory fees and other accrued expenses approximate fair value.

For the determination of the fair value of the venture capital investments refer to notes 5.2 and 7.

The fair value of the loans payable to related party and convertible notes is determined by discounting the future contractual cash flows. For loans payable to related party and the convertible notes in the six months period ended March 31, 2019, the applied discount factor of 12.2% is determined based on the Capital Asset Pricing Model (CAPM) (Previous year ended September 30, 2018: 12.2%).

Notes to the condensed financial statements for the six months ended March 31, 2019

7. Venture capital investments, held by New Venturetec Ltd.

7.1. List of venture capital investments

		Approximate paid-in capital		Approximate percentage held	
		31.03.2019	30.09.2018	31.03.2019	30.09.2018
Biotechnology	**Place of business**	**USD million**	**USD million**	**%**	**%**
Osiris Therapeutics	USA	284	284	11.9	11.9
Myriad Genetics	USA	1,046	916	0.2	0.2

As of March 31, 2019 and as of September 30, 2018, the Company's venture capital investments are primarily in the form of common or preferred shares.

7.2. Movements of cost and changes in fair value, current period

	Cost 01.10.2018	Additions	Disposals	Cost 31.03.2019	Fair value 31.03.2019
	USD	USD	USD	USD	USD
Biotechnology					
Osiris Therapeutics	41,443,340	0	0	41,443,340	77,962,719
Myriad Genetics	7,161,075	0	0	7,161,075	5,312,000
Total Investments	**48,604,415**	**0**	**0**	**48,604,415**	**83,274,719**

	Cumulative fair value adjustments 01.10.2018	Gains	Losses	Disposals [1]	Translation adjustment	Cumulative fair value adjustments 31.03.2019
		USD	USD	USD	USD	USD
Biotechnology						
Osiris Therapeutics	4,103,301	33,009,847 [2]	0	0	(593,769)	36,519,379
Myriad Genetics	198,925	0	(1,944,738) [3]	0	(103,262)	(1,849,075)
Total investments	**4,302,226**	**33,009,847**	**(1,944,738)**	**0**	**(697,031)**	**34,670,304**

Osiris Therapeutics, Inc. ("Osiris"), announced on April 17, 2019, that it has completed the previously announced sale of Osiris to Smith & Nephew plc ("Smith & Nephew") through the consummation of a merger of Osiris with and into an indirect wholly-owned subsidiary of Smith & Nephew (the "Subsidiary") without a vote of the Osiris stockholders in accordance with Section 3-106.1 of the Maryland General Corporation Law. More than a majority of the outstanding shares of Osiris common stock were tendered in the tender offer. New Venturetec Ltd. did not tender its shares, which have been converted into the right to receive $19.00 per share in cash in the second-step merger.

1 Generally, a positive amount reflects cumulative loss on disposal of an investment, a negative amount a cumulative realized gain on disposal of an investment.
2 Based on quoted price of the Osiris Therapeutics shares on NASDAQ (OSIR).
3 Based on quoted price of the Myriad Genetics shares on NASDAQ (MYGN).

7.3. Movements of cost and changes in fair value, prior year

	Cost as transferred from Venturetec Inc. [1] USD	Additions USD	Disposals USD	Cost 30.09.2018 USD	Fair value 30.09.2018 USD
Biotechnology					
Osiris Therapeutics	41,443,340	0	0	41,443,340	45,546,641
Myriad Genetics	7,454,500	0	(293,425)	7,161,075	7,360,000
Total Investments	**48,897,840**	**0**	**(293,425)**	**48,604,415**	**52,906,641**

	Gains USD	Losses USD	Disposals [2] USD	Translation adjustment USD	Cumulative fair value adjustments 30.09.2018 USD
Biotechnology					
Osiris Therapeutics	3,795,602 [3]	0	0	307,699	4,103,301
Myriad Genetics	260,939 [4]	0	(144,911)	82,897	198,925
Total investments	**4,056,541**	**0**	**(144,911)**	**390,596**	**4,302,226**

1 The amounts shown as cost reflect the fair value of the transferred items as of the date of the transfers which took place in second half of financial year 2017/18 (Historical cost as acquired by the dissolved subsidiary amounted to USD 29,161,324 and cumulative fair value adjustments amounted to USD 19,736,516)
2 Generally, a positive amount reflects cumulative loss on disposal of an investment, a negative amount a cumulative realized gain on disposal of an investment.
3 Based on quoted price of the Osiris Therapeutics shares on NASDAQ (OSIR).
4 Based on quoted price of the Myriad Genetics shares on NASDAQ (MYGN).

8. Detailed information on non-consolidated and dissolved subsidiary Venturetec Inc.

New Venturetec Ltd. has dissolved its fully owned subsidiary Venturetec Inc., Tortola, as of April 1, 2018 and transferred all assets held by the dissolved subsidiary to its direct ownership during the second half of the financial year ending September 30, 2018. As of March 31, 2019, New Venturetec Ltd. holds all of its venture capital investments directly.

Prior to the dissolution of Venturetec Inc., New Venturetec Ltd. held its investments through Venturetec Inc. Based on the requirements of IFRS 10, the 100% owned legal subsidiary Venturetec Inc., Tortola was considered to meet the definition of an investment entity for IFRS purposes, and was to be fair valued and classified as level 2 investment.

8.1. Investment in non-consolidated (dissolved) subsidiary at fair value through profit or loss

This caption previously included the Company's wholly owned and dissolved subsidiary Venturetec Inc., which was dissolved on April 1, 2018, measured at fair value and classified as level 2 investment. The fair value of the investment in non-consolidated subsidiary is determined as the adjusted net assets of that subsidiary as the underlying assets and liabilities carried in that subsidiary equal or approximate fair value. As the subsidiary holds mostly shares in listed investments, there is no liquidity discount to be applied.

	2018/19 USD	2017/18 USD
Opening Balance as of October 1	**0**	**28,062,042**
Profit / (loss) on investment in non-consolidated subsidiary	0	16,008,619 [1]
Ending balance as at March 31	**0**	**44,070,661**

8.2. Reconciliation of the fair value of the (dissolved) subsidiary

The following table presents a reconciliation of the fair value of the dissolved Venturetec Inc. as reported by New Venturetec Ltd. to the underlying assets and liabilities held by the subsidiary and transferred to the direct ownership of New Venturetec Ltd.

Fair value of Venturetec Inc.	March 31, 2019 USD	March 31, 2018 USD
Venture capital investments	0	41,132,549
Cash and cash equivalents	0	892,473
Current account receivable from New Venturetec Ltd. (shareholder)	0	2,090,679
Accrued advisory fees	0	(45,040)
Total fair value of subsidiary	**0**	**44,070,661**

[1] Including FX profit on translation of USD 632,206

8. Detailed information on non-consolidated and dissolved subsidiary Venturetec Inc. (continued)

8.3. Venture capital investments held by the dissolved non-consolidated subsidiary

8.3.1. Movements of cost and changes in fair value, prior year

	Cost 01.10.2017 USD	Additions USD	Disposals USD	Cost 31.03.2018 USD	Fair value 31.03.2018 USD
Biotechnology					
Osiris Therapeutics	24,173,023	0	0	24,173,023	36,109,049
Myriad Genetics	5,868,501	0	(880,200)	4,988,301	5,023,500
Total Investments	**30,041,524**	**0**	**(880,200)**	**29,161,324**	**41,132,549**

	Cumulative fair value adjustments 01.10.2017 USD	Gains USD	Losses USD	Disposals [1] USD	Cumulative fair value adjustments 31.03.2018 USD
Biotechnology					
Osiris Therapeutics	(5,297,838)	17,233,864 [2]	0	0	11,936,026
Myriad Genetics	1,367,499	0	(1,205,048) [3]	(127,252)	35,199
Total investments	**(3,930,339)**	**17,233,864**	**(1,205,048)**	**(127,252)**	**11,971,225**

[1] Generally, a positive amount reflects cumulative loss on disposal of an investment, a negative amount a cumulative realized gain on disposal of an investment.
[2] Based on quoted price of the Osiris Therapeutics shares on NASDAQ (OSIR).
[3] Based on quoted price of the Myriad Genetics shares on NASDAQ (MYGN)

Notes to the condensed financial statements for the six months ended March 31, 2019

9. Loans payable to related parties

	Six months ended March 31, 2019 USD	Six months ended March 31, 2018 USD
Carrying amount of liability carried forward as of October 1	**7,392,942**	**6,471,413**
Proceeds from increase of loans	0	1,040,582
Interest paid by New Venturetec Ltd.	(152,349)	0
Total changes from financing cash flows	**(152,349)**	**1,040,582**
Suspended redemption of convertible bonds and conversion into loan payable to related parties (non-cash)	0	12,486,993 [1]
Shareholders' contribution in relation to non-market interest rate	0	(331,581) [2]
Interest expenses for the current period	438,486	706,955
Interest paid by non-consolidated subsidiary	0	(136,199)
Currency translation adjustment	(101,473)	199,146
Total other changes (non-cash)	**337,013**	**12,925,314**
Carrying amount of liability as of the end of the period	**7,577,606**	**20,437,309**
Thereof current	7,577,606	19,457,329
Thereof non-current	0	979,980

1) It was agreed to suspend the redemption of CHF 12,000,000 of the convertible bonds - which have been subscribed by Peter Friedli, the chairman of New Venturetec Ltd., due for repayment January 23, 2018 - and to keep as loan payable by applying same terms. On April 20, 2018, the suspended amount was converted into a convertible note by applying same terms.

2) Given the situation of the company at recognition date, the market interest rate used to value the loans at recognition date or at extension of their maturity amounted to 12.2%. The difference between the amount lent and the fair value of the loans are recognized as a shareholders' contribution in equity.

10. Convertible Notes

List of Convertible Notes as of March 31, 2019

Aggregated principal amount	Date of issuance	Interest rate %	Premium %	Maturity	Convertible into shares of the Company	Conversion price
CHF 1,125,000	22.01.18	4.00	n/a	31.12.19	Voluntarily, at the discretion of the holder	CHF 9.50 [1)]
CHF 12,000,000	30.11.18	4.00	1.00	31.12.19	Voluntarily, at the discretion of the holder	CHF 9.50 [2)]

List of Convertible Notes as of March 31, 2018

Aggregated principal amount	Date of issuance	Interest rate %	Maturity	Convertible into shares of the Company	Conversion price
CHF 1,125,000	22.01.18	4.00	31.12.19	Voluntarily, at the discretion of the holder	CHF 9.50 [1)]

1) Andreas von Sprecher, member of the Board of New Venturetec Ltd. subscribed to CHF 50,000 of the convertible notes issued January 22, 2018. In accordance with the terms and conditions of the convertible notes, Andreas von Sprecher has the right to voluntarily convert his holdings into 5,263 shares of New Venturetec Ltd.

2) Peter Friedli, the chairman of New Venturetec Ltd., subscribed to CHF 12,000,000 of the convertible notes issued April 20, 2018 and prolonged on November 30, 2018. On August 21, 2018, Peer Friedli assigned the convertible note to Friedli Corporate Finance GmbH, Zug, with all rights and obligations. Friedli Corporate Finance GmbH is fully owned and controlled by Peter Friedli. In accordance with the terms and conditions of the convertible notes, Friedli Corporate Finance GmbH has the right to voluntarily convert its holdings into 1,263,157 shares of New Venturetec Ltd. The premium of 1% p.a. is payable at redemption; if converted no premium. On April 15, 2019, the Note is converted, see also note 16.

Convertible Notes	Six months ended March 31, 2019 USD	Six months ended March 31, 2018 USD
Carrying amount of liability carried forward as of October 1	**13,331,885**	**0**
Proceeds from issue of convertible notes (CHF 1,125,000)	0	1,170,656
Interest paid	(357,154)	0
Total changes from financing cash flows	**(357,154)**	**1,170,656**
Prolongation of convertible notes (CHF 12,000,000)		
- derecognition of existing convertible note	(12,015,620)	0
- recognition of new convertible note	11,156,670 [1)]	0
Conversion option recognized in equity	0	(159,371) [1)]
Interest expenses for the current period	759,042	23,486
FX Adjustments	(186,043)	7,645
Total other changes (non-cash)	**(285,951)**	**(128,240)**
Carrying amount of liability as of the end of the period	**12,688,780**	**1,042,416**
Thereof current	12,688,780	0
Thereof non-current	0	1,042,416

1) Given the current situation of the company, the market interest rate used to value the loans at prolongation / recognition date amounted to 12.2% (Previous period: 12.2%). The difference between the amount lent and the fair value of the liability component of the convertible notes on prolongation / recognition in the amount of USD 858,050 has been recognized as a conversion option in equity.

11. Convertible Bonds

	Six months ended March 31, 2019 USD	Six months ended March 31, 2018 USD
Carrying amount of liability carried forward as of October 1	**0**	**15,959,264**
Interests paid out	0	(622,365)
Redemption in cash on due date	0	(3,178,980)
Total changes from financing cash flows	**0**	**(3,801,345)**
Interest expenses for the current period	0	212,320
Suspended redemption of convertible bonds and conversion into loan payable to related parties (non-cash)	0	(12,486,993)
FX Adjustments	0	116,754
Total other changes (non-cash)	**0**	**(12,157,919)**
Carrying amount of liability as of the end of the period	**0**	**0**

On January 23, 2014, New Venturetec Ltd. issued convertible bonds with the aggregated principal amount of CHF 15,055,000 and an interest rate of 4% per annum. The bonds were convertible at a conversion price of CHF 9.50 per share. The bonds became payable on January 23, 2018, whereby none of the bonds were converted.

CHF 12,000,000 of the convertible bonds have been subscribed by Peter Friedli. It was agreed to suspend the redemption of this amount due to Peter Friedli and to keep as loan payable by applying same terms. On April 20, 2018, the suspended amount was converted into a convertible note by applying same terms.

As of March 31, 2019 and 2018, the Company has no outstanding convertible bonds.

12. Share capital and capital management

12.1. History of changes in share capital

The share capital as of March 31, 2019 of CHF 30,000,000 (USD 20,785,350) consisted of 5,000,000 bearer shares with a par value of CHF 6.00 each fully paid in.

The conversion options / own equity instruments comprise the amount allocated to the equity component for the convertible notes issued by New Venturetec Ltd.

Conditional share capital: The share capital may be increased by a maximum amount of CHF 10,200,000 through the issue of a maximum of 1,700,000 registered shares to be fully paid-in with a nominal value of CHF 6.00 each through the exercise of conversion or option rights in connection with convertible notes or bonds or similar instruments that are or may be issued by the Company.

12.2. Significant shareholders

As of March 31, 2019 the following shareholders filed a holding of 3% or more of the total outstanding shares of the Company to SIX Swiss Exchange:

Between 5% and 10%

- Reinhard and Rosa Siegrist, with Georges Mari and Rossier, Mari & Associates AG, Zurich, all together as a group represented by Georges Mari, Zurich [1)]
- Alexander and Chantal Biner, through 4iS Four Eyes AG, St. Gallen [1)]

Between 3% and 5%

- RM Strategic Fund
- Guido Erni, Untersiggenthal [1)]

12.3. Capital management

The objective of the Company is to achieve long term capital appreciation through equity and debt investments in start-up, emerging and growth companies which the Company believes offer significant growth opportunities. The Company identifies successful and promising companies and then actively work with management over a five to ten year time horizon.

The investment decisions will be based upon (i) the Company's ability to identify companies which can successfully utilize capital at an early stage in their life cycle, (ii) carefully selected or assessed management teams, (iii) strategic advice for positioning such companies in high growth markets promising to generate public interest at a future date and (iv) an influence on the portfolio companies.

The Company measures its performance based on the development of its Net Asset Value (NAV). The NAV per share is a figure which is calculated on a regular, consistent basis to approximately reflect the intrinsic value of one share of the Company. The NAV is expected to serve as an indicator for the price of the shares of the Company. The NAV per share is calculated on a monthly basis by dividing the value of the net assets of the Company (the value of its assets less its liabilities) by the total number of shares outstanding.

It is not the aim of the Company to leverage its equity for the purpose of making investments. Nevertheless, the Company may carry some debt in order to balance the availability of liquidity and to avoid dilution of its investments. The Company's debt financing is primarily provided by Peter Friedli and/or Friedli Corporate Finance GmbH through accrued management fees and accrued performance fees that were converted into loans payable (see note 14.3) and convertible notes (see note 10).

It is not the Company's policy to pay out any dividends.

[1] Significant shareholders are reported as per March 31, 2019. However on April 9, 2019, Reinhard and Rosa Siegrist, Georges Mari, Rossier, Mari & Associates AG, Alexander and Chantal Biner and Guido Erni reported having formed a group with effective date April 3, 2019, to coordinate their voting rights, with aggregate holdings of between 20% and 25% of the total outstanding shares of the Company.

Notes to the condensed financial statements for the six months ended March 31, 2019

Notes to the statement of comprehensive income

Note to the cash flow statement

13. Additional information to the cash flow statement

Significant non-cash transactions:

Related to the six months period ended March 31, 2019

- USD 12,015,620 (CHF 12,000,000) of the convertible note which became due November 30, 2018 was extended to December 31, 2019 through re-issuance and resulting in a derecognition of the old liability and recognition of the new liability.

Related to the six months period ended March 31, 2018

- USD 12,486,993 (CHF 12,000,000) of the convertible bonds which became due January 23, 2018, was suspended from redemption and was converted into a loan payable to related parties.

Notes to the condensed financial statements for the six months ended March 31, 2019

Other notes

14. Related parties

14.1. Investment Advisor

Since January 1, 2013, Madison Investment Advisor, Inc., Panama is the investment advisor of New Venturetec Ltd. The investment advisor supports and advises the Board on specific duties with regards to the selection, purchase, sale, structure and disposal of the subsidiary's investments. Starting October 1, 2014, the Board of Directors and the Investment Advisor agreed to an all-inclusive fee of 1.00% of the net asset value per annum without any additional costs to be reimbursed by the Company. Advisory fees for the investment advisor were recognized in and paid by the non-consolidated subsidiary, Venturetec Inc., until June 30, 2018, as Venturetec Inc., was the contracting partner of the advisory agreement with the investment advisor. Due to the dissolution of Venturetec Inc., New Venturetec Ltd. entered as new contracting partner into the advisory agreement effective July 1, 2018. The advisory fees for the investment advisor are recognized in and paid by New Venturetec Ltd. starting July 1, 2018, which are included within New Venturetec Ltd.'s profit or loss statement.

Peter Friedli is the President and owner of Madison Investment Advisor, Inc., Panama and at the same time is the Chairman of the Board of Directors of New Venturetec Ltd. Furthermore, he is also Chairman of the Board of Directors of Osiris Therapeutics Inc. As Chairman of the Board of Directors of the Investment Advisor of New Venturetec Ltd. and other investment companies, he may be able to exercise significant influence or control over the Company's investees.

14.2. Board of Directors

USD 20,074 were accrued as fees to the Board Directors for the period under review and USD 40,148 were paid out related to accrued fees for prior periods (2018: USD 25,837 accrued and USD 51,674 paid out). These fees are included in the administration cost. However in previous year, they were effectively paid through a bank account of the dissolved subsidiary and credited to New Venturetec Ltd.'s current account with the subsidiary.

14. Related parties (continued)

14.3. Loans and convertible notes payable to related parties

All loans payable to related parties were entered into with Peter Friedli at their issuance date. On August 21, 2018, Peter Friedli assigned all promissory notes and convertible notes payable by the Company to him to Friedli Corporate Finance GmbH, Zug with all rights and obligations. Friedli Corporate Finance GmbH is fully owned and controlled by Peter Friedli and he is the beneficial owner.

Loans payable to related parties as of 31.03.2019	**Principal**	**Accrued Interests**	**Total**
	USD	**USD**	**USD**
4% secured promissory note [1) 4) 5)]	5,017,307	51,133	5,068,440
4% secured promissory note [2) 4) 5)]	1,478,778	15,071	1,493,849
4% + 3% secured promissory note [3) 4) 5)]	969,351	45,966	1,015,317
Total	**7,465,436**	**112,170**	**7,577,606**
Thereof current	7,465,436	112,170	7,577,606
Thereof non-current	0	0	0

Loans payable to related parties as of 30.09.2018	**Principal**	**Accrued Interests**	**Total**
	USD	**USD**	**USD**
4% secured promissory note [1) 4) 5) 6)]	4,892,579	51,847	4,944,426
4% secured promissory note [2) 4) 5) 6)]	1,442,016	15,281	1,457,297
4% + 3% secured promissory note [3) 4) 5)]	959,977	31,242	991,219
Total	**7,294,572**	**98,370**	**7,392,942**
Thereof current	6,334,595	67,128	6,401,723
Thereof non-current	959,977	31,242	991,219

Convertible notes payable to related parties as of 31.03.2019	**Principal**	**Accrued Interests**	**Total**
	USD	**USD**	**USD**
4% + 1% convertible notes (31.12.19 - current) payable to Friedli Corporate Finance GmbH [7)]	11,449,092	160,755	11,609,847
4% convertible notes (31.12.19 - current) payable to Andreas von Sprecher	47,450	502	47,952

Convertible notes payable to related parties as of 30.09.2018	**Principal**	**Accrued Interests**	**Total**
	USD	**USD**	**USD**
4% convertible notes (30.11.18 - current) payable to Friedli Corporate Finance GmbH [6) 7)]	12,061,194	217,332	12,278,526
4% convertible notes (31.12.19 - non current) payable to Andreas von Sprecher	46,307	509	46,816

1) On May 2, 2014, outstanding promissory notes of CHF 2,816,269 and CHF 2,273,041 due to Peter Friedli were combined and replaced by a 4% secured promissory note due to Peter Friedli in the total amount of CHF 5,089,310, due on December 31, 2014. On August 21, 2018, Peter Friedli assigned the promissory note to Friedli Corporate Finance GmbH, Zug. The term of the note will be automatically extended by six months on each consecutive maturity date and the current due date is June 30, 2019. The note can be terminated on each maturity date by either party upon a 3 month written notice.

14. Related parties (continued)

14.3 Loans and convertible notes / bonds payable to related parties (continued)

2) On April 23, 2015, New Venturetec Ltd. issued a 4% secured promissory note due to Peter Friedli in the amount of CHF 1,500,000, due on December 31, 2015. On August 21, 2018, Peter Friedli assigned the promissory note to Friedli Corporate Finance GmbH, Zug. The term of the note will be automatically extended by six months on each consecutive maturity date and the current date is June 30, 2019. The note can be terminated on each maturity date by either party upon a 3 month written notice.

3) On January 22, 2018, New Venturetec Ltd. issued a 4% secured promissory note due to Peter Friedli in the amount of CHF 1,000,000, due on December 31, 2019, redeemable with an annualized premium of 3% per annum. On August 21, 2018, Peter Friedli assigned the promissory note to Friedli Corporate Finance GmbH, Zug.

4) Given the current situation of the company, the market interest rate used to value the loans at the last extension date amounted to 12.2% (September 30, 2018: 12.2%). The difference between the amount lent and the fair value of the promissory notes on initial recognition has been recognized as shareholders' contribution in equity.

5) Secured by all tangible and intangible assets of New Venturetec Ltd.

6) Subject to subordination agreement with regard to the capital loss in the statutory financial statements of New Venturetec Ltd. in accordance with Art. 725 para. 1 CO. in previous years. Effective with November 2, 2018, the subordination agreement was terminated.

7) On November 2, 2018, Friedli Corporate Finance GmbH and New Venturetec Ltd. agreed to prolong the CHF 12 million convertible note with following terms: due December 31, 2019; secured; voluntarily convertible at CHF 9.50 per share; interest rate 4% p.a.; premium 1% p.a. payable at redemption; if converted no premium.

14.4. Interests on loans, convertible notes and bonds payable to related parties

During the reporting period under review, interests on loans, convertible notes and bonds payable to related parties were recorded in profit or loss as follows:

Interests on loans and convertible notes / bonds payable to related parties	Six months ended 31.03.2019 USD	Six months ended 31.03.2018 USD
4% secured promissory notes to Friedli Corporate Finance GmbH / Peter Friedli	380,708	404,615
4% + 3% secured promissory notes to Friedli Corporate Finance GmbH / Peter Friedli	57,777	22,079
4% convertible note to Friedli Corporate Finance GmbH	241,625	0
4% + 1% convertible note to Friedli Corporate Finance GmbH	454,799	0
4% convertible note to Andreas von Sprecher	2,783	1,045
4% loan related to suspended redemption due to Peter Friedli	0	280,261
4% convertible bonds to Peter Friedli	0	169,235
4% convertible bonds to Andreas von Sprecher	0	705
Total interests on loans from related parties	**1,137,692**	**877,940**

[1] See note 14.3.

14. Related parties (continued)

14.5. Related party transactions

- Interest on loans payable and convertible bonds to related parties in the amount of USD 1,137,692 (previous period: USD 877,940) were recognized in the reporting period, whereof USD 487,924 (previous period USD 634,339) was paid out. The difference of USD 649,768 (previous period: USD 243,702) reflects the amortization of the difference between the fair value of the loans payable and their amortized cost at the time when the maturity date of the loans were extended and variation of accrued interests. See note 14.3.
- USD 20,074 were accrued as fees to the Board Directors for the period under review and USD 40,148 were paid out related to accrued fees for prior periods (2018: USD 25,837 accrued and USD 51,674 paid out).
- Advisory fees, due to Madison Investment Advisor, in the total amount of USD 218,730 were recognized for the investment advisor in the reporting period (previous period: Total advisory fees USD 67,451 were recognized in the non-consolidated and dissolved subsidiary).

15. Earnings per Share

The calculation of diluted earnings per share has been based on the following profit attributable to ordinary shareholders and the weighted-average number of ordinary shares outstanding after adjustment for the effects of all dilutive potential ordinary shares.

	Six months ended 31.03.2019 USD	Six months ended 31.03.2018 USD
Profit attributable to ordinary shareholders (basic)	29,498,351	14,181,802
Interest expenses on convertible notes/bonds, net of tax	759,042	235,806
Profit attributable to ordinary shareholders (diluted)	**30,257,393**	**14,417,608**
Weighted-average number of ordinary shares		
- outstanding as of September 30 (basic)	5,000,000	5,000,000
- that would be issued at conversion	1,381,578	1,036,883
Total weighted-average number of ordinary shares (diluted)	**6,381,578**	**6,036,883**
Earnings per share (basic)	**5.90**	**2.84**
Earnings per share (diluted)	**4.74**	**2.39**

16. Subsequent events

The financial statements were authorized for issue by the Board of Directors on May 3, 2019.

On April 15, 2019, the CHF 12mio convertible note held by Friedli Corporate Finance GmbH, Zug, a company fully controlled and owned by Peter Friedli, Chairman of the Board of New Venturetec Ltd., was converted into 1,263,157 shares of New Venturetec Ltd. with nominal value of CHF 6.00 each. On April 26, 2019 an additional CHF 500,000 convertible note held by third parties has been converted into 52,629 shares. As of May 3, 2019, there are 6,315,786 shares outstanding.

On April 17, 2019, New Venturetec Ltd.'s major investment, Osiris Therapeutics, Inc. announced that it has completed the previously announced sale of Osiris to Smith & Nephew plc ("Smith & Nephew") through the consummation of a merger of Osiris with and into an indirect wholly-owned subsidiary of Smith & Nephew (the "Subsidiary") without a vote of the Osiris stockholders in accordance with Section 3-106.1 of the Maryland General Corporation Law. More than a majority of the outstanding shares of Osiris common stock were tendered in the tender offer. New Venturetec Ltd. did not tender its shares, which have been converted into the right to receive $19.00 per share in cash in the second-step merger.

The Board of Directors is not aware of any further events between March 31, 2019 and May 3, 2019, which would require adjustment to the carrying amounts of the Company's assets and liabilities as of March 31, 2019 or would require disclosure under this heading.

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The following text is an extract from the Osiris Therapeutics, Inc. annual report for the fiscal year ended December 31, 2018 (Form 10k). The terms "Osiris," "we," "us," and "our" means Osiris Therapeutics, Inc.

Risk Factors

We are subject to numerous risks and uncertainties. In addition to the other information contained in this report, you should carefully consider the risks and uncertainties described below. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impact our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of known and unknown risks including the risks described below or elsewhere in this report.

Risks Related to the Transaction

On March 12, 2019, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Parent Holdco, Parent and Papyrus Acquisition Corp., pursuant to which, and upon the terms and subject to the conditions described therein, Papyrus Acquisition Corp. will commence a cash tender offer (the "Offer") to acquire all of the outstanding shares of the Company's common stock at a purchase price of $19.00 per share, in cash, without interest, subject to any required withholding of taxes. Following the completion of the Offer, subject to the satisfaction or waiver of certain customary conditions set forth in the Merger Agreement, Papyrus Acquisition Corp. will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Parent, pursuant to the procedure provided for under Section 3- of the MGCL, without any stockholder approvals. We refer to this as the "Merger," and the Offer and the other transactions contemplated by the Merger Agreement as the "Transaction".

Failure to complete the Transaction could negatively impact the price of our common stock, as well as our future business and financial results.

The Merger Agreement contains a number of conditions that must be satisfied or waived prior to the completion of the Transaction. We cannot assure you that all of the conditions to the Transaction will be so satisfied or waived. If the conditions to the Merger are not satisfied or waived, we may be unable to complete the Transaction.

If the Transaction is not completed, our ongoing business may be adversely affected as follows: (i) we may experience negative reactions from the financial markets, including negative impacts on the market price of our common stock; (ii) some of management's attention will have been directed to the Transaction instead of being directed to our own operations and the pursuit of other opportunities that could have been beneficial to us; (iii) the manner in which customers, suppliers and other third parties perceive us may be negatively impacted, which in turn could affect our ability to compete for business; (iv) we may experience negative reactions from employees; (v) we will have expended time and resources that could otherwise have been spent on our existing business; and (vi) we may be required, in certain circumstances, to pay a termination fee of approximately $18.7 million, as provided in the Merger Agreement.

Additionally, in approving the Merger Agreement, the Board of Directors considered a number of factors and potential benefits, including the fact that the Merger consideration to be received by holders of our common stock represented a 37% premium to the Company's 90-day volume-weighted average stock price. If the Merger is not completed, neither the Company nor the holders of our common stock will realize this benefit of the Transaction. Moreover, we would also have nevertheless incurred substantial transaction-related fees and costs and the loss of management time and resources.

A significant delay in consummating or a failure to consummate the Transaction could have a material adverse effect on the price of our common stock and our operating results.

Because the Transaction is subject to certain closing conditions, it is possible that the Transaction may not be completed or may not be completed as quickly as expected. If the Transaction is not completed, it could have a material adverse effect on the price of our common stock. In addition, any significant delay in consummating the Transaction could have a material adverse effect on our operating results and adversely affect our relationships with customers and suppliers and would likely lead to a significant diversion of management and employee attention.

Expenses related to the proposed Transaction are significant and will adversely affect our operating results.

We have incurred and expect to continue to incur significant expenses in connection with the proposed Transaction, including legal and investment banking fees. We expect these costs to have an adverse effect on our operating results. If the Transaction is not consummated, we may under certain circumstances be required to pay to Parent a termination fee of approximately $18.7 million. Our financial position and results of operations would be adversely affected if we were required to pay the termination fee to Parent.

We are subject to business uncertainties and contractual restrictions while the Transaction is pending, which could adversely affect our business.

The Merger Agreement requires us to act in the ordinary course of business and restricts us, without the consent of Parent from taking certain specified actions until the proposed Transaction occurs or the Merger Agreement terminates. These restrictions may prevent us from pursuing otherwise attractive business opportunities and making other changes to our business before

completion of the Transaction or, if the Transaction is not completed, termination of the Merger Agreement.

Uncertainties associated with the Transaction may cause a loss of management and other key employees and disrupt our business relationships, which could adversely affect our business.

Uncertainty about the effect of the Transaction on our employees, customers and suppliers may have an adverse effect on our business. These uncertainties may impair our ability to attract, retain and motivate key personnel until the Transaction is completed and for a period of time thereafter. Employee retention may be particularly challenging during the pendency of the Transaction. If key employees depart and as we face additional uncertainties relating to the Transaction, our business relationships may be subject to disruption as customers, suppliers and other third parties attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than the Company. If key employees depart or if our existing business relationships suffer, our results of operations may be adversely affected. The adverse effects of such disruptions could be further exacerbated by any delay in the completion of the Transaction.

Risks Related to Our Business

Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.

The following factors, among others, may negatively affect our operating results:

- failure to obtain reimbursement approvals by, and adequate and timely reimbursements from, third-party payors, such as Medicare and private health plans, for our products;
- removal of our products from the Federal Supply Schedule or change in the prices that government customers will pay for our products;
- our ability to attract and retain key personnel;
- the announcement or introduction of new or improved products by our competitors;
- our ability to obtain the necessary quantities of human tissue to manufacture our products;
- our ability to upgrade and develop our systems and infrastructure to accommodate our growth, including adding more manufacturing capacity to enable us to continue to meet market demand;
- our ability to manage our relationships with third parties that help us research, develop, manufacture, market, and distribute our products;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations, and infrastructure;
- our ability to comply with regulatory requirements related to the marketing, manufacturing and distribution of our products and product candidates, including FDA regulations; and
- general economic conditions as well as economic conditions specific to the healthcare industry.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although certain of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenue relative to our planned expenditures would have an immediate adverse effect on our business, financial condition and results of operations. Further, as a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service or marketing decisions that could have a material adverse effect on our business, financial condition and results of operations.

We have a history of operating losses and may not achieve or sustain profitability.

We have incurred losses in each year since our inception (except fiscal years 2009, 2010, 2011, 2013, 2017 and 2018), and may incur additional losses in the future. As of December 31, 2018, we had an accumulated deficit of approximately $205.4 million. In earlier years, these losses resulted principally from costs incurred in our R&D programs. In recent years, these losses resulted principally from our growing sales and marketing expenses, primarily due to the expansion of our sales force which was internalized in 2014, and from our growing general and administrative expenses. Our general and administrative expenses included approximately $3.8 million and $9.5 million in 2018 and 2017, respectively, of legal and accounting related to the restatement of our 2015 interim financial statements and the restatement of our 2014 financial statements included in the 2014 Form 10-K/A, as more fully described in the comprehensive Annual Report on Form 10-K for the fiscal years ended December 31, 2015, 2016 and 2017 (the "Restatement").

We expect to continue to incur significant operating expenses in the foreseeable future as we seek to:

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- continue to add sales, operational, compliance, and financial personnel either through additional employees or outsourcing, consistent with expanding our operations and improving our internal control over financial reporting;
- expand our manufacturing capacity;
- continue to pursue clinical studies for our products to support our reimbursement efforts;
- manage regulatory issues and requirements related to the marketing, manufacturing, and distribution of our products and product candidates, including issues related to FDA regulation and third-party payor reimbursement; and
- maintain, expand and protect our intellectual property.

The extent of our future operating losses or profits is highly uncertain, and we may not maintain profitability. If we are unable to achieve and then maintain profitability, the market value of our common stock will decline.

We continue to expand our sales and marketing capabilities, and there can be no assurance that these efforts will result in significant increases in sales.

Since 2014, we have been engaged in a major initiative to build and expand our internal sales and marketing capabilities. As a result, we have and are continuing to hire direct sales personnel for certain of our products to allow us to reach new customers. Due to the unique nature of our products, we spend significant time and resources on recruiting, training, retaining, motivating and managing our sales personnel. The increased expenses associated with these selling efforts impact our operating results, and there can be no assurance that we will be successful in significantly increasing sales of our products.

We may have difficulty managing growth in our business, which could have a material adverse effect on our business, financial condition, and results of operations.

As we expand our activities there will be additional demands on our financial, operational and management resources. To manage the growth of our operations and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative and operations staff. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities. The failure to manage growth effectively could have a material adverse effect on our business, financial condition and results of operations.

Our revenues depend on obtaining coverage and adequate reimbursement from public and private insurers and health systems.

Our success depends on the extent to which reimbursement for the costs of our products will be available from third-party payors, such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. A significant number of government and private third-party payors currently do not provide coverage and reimbursement for our products. If we are not successful in obtaining coverage and adequate reimbursement for our products from more third-party payors, our ability to sell our products will be adversely affected. Therefore, our ability to grow our revenues is dependent on our ability to meet the requirements for coverage of additional third-party payors, and to negotiate acceptable reimbursement with such payors once our products have been approved for coverage. Even if we do succeed in obtaining widespread coverage and adequate reimbursement for our products, future changes in coverage and reimbursement policies could have a negative impact on our business, financial condition and results of operations.

Our products may have higher costs than more traditional products, due to the higher cost and complexity associated with their research, development and production, and the complexity associated with their distribution. This higher cost and complexity can make it more difficult to obtain adequate coverage and reimbursement.

Our products may have higher costs or fees associated with them compared with more traditional products, due to the higher cost and complexity associated with their research, development and production, and the complexity associated with their distribution—which requires special handling, storage and shipment procedures and protocols. This, in turn, makes it more difficult for us to obtain approval for coverage and reimbursement from third-party payors for our products and the procedures in which they are used, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payors may also deny coverage because the product has not received approval from the FDA or other government regulators that they believe is necessary, or they believe that the product is experimental, unnecessary or inappropriate.

Even though we are not required to conduct clinical trials in order to market our products in the United States, we may nevertheless be required to conduct one or more clinical studies, and to publish one or more peer reviewed journal articles supporting the products, before we are able to obtain third-party reimbursement. We may also be required to conduct additional clinical studies that compare the cost effectiveness of our products to other available therapies before third-party payors will provide reimbursement. Conducting clinical studies is expensive and results in delays in wide scale commercialization and reimbursement. In addition, even if our products otherwise meet the requirements for reimbursement, pricing negotiations with third-party payors may take months or longer and result in significant delay in obtaining approval for reimbursement.

Coverage and reimbursement policies also sometimes differ depending upon the setting in which the product is to be used. The use of our products in a hospital setting as part of a surgical or other more extensive procedure may have a coverage and reimbursement pathway that differs from a use in an outpatient setting for a more narrowly defined procedure.

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Thus, for example, the coverage and reimbursement pathway for Grafix—which we expect to be used more often in an outpatient setting—may differ from that for BIO[4]—which we expect to be used more often in an in-patient hospital setting as part of a surgical procedure. These differences may limit or make coverage and reimbursement more difficult for some products as compared to others, and influence our product development and marketing efforts in ways that may ultimately prove to be detrimental to our business. Payors' coverage and reimbursement policies also are subject to change, and the policies in effect at the time a product is marketed may be different from the policies in place when a coverage and reimbursement strategy was developed.

In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit coverage and reimbursement for newly approved healthcare products. In particular, third-party payors may limit the indications for which they will reimburse patients who use our products, or they may not provide reimbursement for our products separately from the procedures in which they are used, to encourage providers to select products based on cost-effectiveness or for other reasons. Cost-control initiatives could decrease the price for our products, which would result in lower product revenue to us.

To continue our commercial expansion, we must convince more physicians that our products are appropriate alternatives to traditional methods and products and that our products should be used in their procedures.

While many physicians are using our products, we must continue our efforts to convince other physicians that our products are appropriate alternatives to traditional methods and products. We believe physicians will only adopt our products if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to conventional methods. Physicians may be slow to change their practices for the following reasons, among others:

- their lack of experience in the field using our products;
- lack of evidence supporting additional patient benefits and our products over conventional methods;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of reimbursement from third-party payors;
- the exclusion of our products on the formulary of their affiliated hospital or group purchasing organization ("GPO"), which would preclude their use of our product; and
- the time that must be dedicated to training physicians on how to use our products.

In addition, hospital acquisition decisions often are affected by physicians' assessments of products. If physicians do not support adoption of our products or if we are unable to demonstrate favorable long-term clinical data, hospitals may not use our products, which would significantly reduce our ability to achieve expected revenue.

The potential of our products under development may not be realized.

We are continually evaluating the potential of our current products and products under development. Our products are susceptible to various risks, including undesirable and unintended side effects, inadequate efficacy or other characteristics that may prevent or limit their commercial use, or if required, pre-marketing approval. We have invested substantial time and resources in developing and commercializing GrafixPL PRIME using our novel Prestige Lyotechnology, a proprietary method to preserve living cells and tissues at room temperatures. Development and commercialization of additional products using Prestige Lyotechnology or new technologies will require additional research, clinical evaluation, significant marketing efforts and substantial additional investment before they can provide us with any revenue. Despite our efforts, any such products may not become commercially successful products for a number of reasons, including:

- we may experience delays in our development programs;
- any products that are approved may not be accepted in the marketplace by patients, physicians, or payors;
- we may not be able to manufacture any such products in sufficient commercial quantities; and
- rapid technological change may make such products obsolete.

If the potential of our products is not realized, the value of our products, technology and development programs could be significantly reduced.

Some product development programs are based on novel technologies, which are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our technology platforms and product candidates creates significant challenges in regards to product development and optimization, processing and manufacturing, government regulation and/or approval, third-party reimbursement and market acceptance. Therefore, the pathway to development and commercialization of our products may be more complex and lengthy than other products. Additionally, tissue- and cell-based products are subject to donor-to-donor variability, which can make standardization more difficult. As a result, the development and commercialization pathway for our products is subject to uncertainty.

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We depend on key personnel.

Our current and future success depends to a significant extent on the skills, experience and efforts of our scientific, management, technical and sales personnel. None of our employees is employed for a specified term, and we have experienced significant turnover. Competition for personnel is intense. We may be unable to retain our current personnel or attract or integrate other qualified scientific, management, technical or sales personnel in the future which could harm our business and might significantly delay or prevent the achievement of research, development, sales or other business objectives.

We are in a highly competitive and evolving field and face competition from well‑established tissue product manufacturers as well as new market entrants.

Our business is in a very competitive and evolving field. Competition from other companies and from research and academic institutions is intense and widespread, expected to increase, subject to rapid change and could be significantly affected by new product introductions. The presence of this competition in our market may lead to pricing pressure, which would limit our ability to sell our products at a price that would make us profitable or prevent us from selling our products at all. Our ability to successfully compete will depend on whether we can perfect and protect our intellectual property rights related to our technologies as well as to develop new technologies and new applications for our technologies. Our failure to compete effectively would have a material adverse effect on our business, financial condition and results of operations.

Our products could become obsolete due to rapid technological change.

The technologies underlying our products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products or processes with significant advantages over the products that we offer or are developing. Any such occurrence could have a material adverse effect on our business, financial condition and results of operations.

Many of our competitors have greater resources or capabilities than we have, or may succeed in developing new or better products more quickly than we do.

In the marketplace, we compete with other companies and organizations that are marketing or developing products competitive with Grafix, Stravix, and our other products and products under development. In many cases, the competing product or candidate is based on bioengineering or other technologies. Companies competing with our products include, but are not limited to: Organogenesis Inc., the manufacturer of Apligraf® and Dermagraft®, MiMedx Group, Inc., the manufacturer of EpiFix®, and Integra LifeSciences Corporation, the manufacturer of Integra, all of which compete with Grafix and Stravix. BIO4 competes with bone tissue products such as Osteocel® marketed by NuVasive, Inc. and Trinity® marketed by Orthofix International NV, while Cartiform competes with cartilage allografts such as ProChondrix® marketed by AlloSource and DeNovo® marketed by Zimmer Biomet Holdings, Inc. In addition to those listed above, we have other existing and potential competitors developing a variety of products for the same conditions for which we market our products. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in R&D and more established marketing and distribution capabilities.

The biotechnology industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Because FDA approval is generally not required for tissue‑based products which are not more than minimally manipulated, competitors might choose to enter this market and produce a substantially similar product, and we may not be able to prevent the marketing and distribution of any such similar products by others. Should others produce a substantially similar product or a new product that renders our current or future products obsolete, we could be subject to increased competition and our potential revenue from distribution of these products may be limited.

Our products are derived from human tissue and therefore have the potential for disease transmission.

Our products consist of human tissue: Grafix is manufactured from human placental tissue; Stravix is manufactured from human placental tissue comprised of amniotic and connective layers of umbilical tissue; BIO4 is manufactured from cadaveric donor bone; and Cartiform is manufactured from cadaveric donor cartilage.

The utilization of human tissue creates the potential for transmission of communicable disease, including, but not limited to, human immunodeficiency virus, Zika virus, viral hepatitis, syphilis, Creutzfeldt‑Jakob disease (the human form of “mad cow” disease) and other viral, fungal or bacterial pathogens. We, and our suppliers of human adult cadaveric bone, cartilage and placenta tissue are required to comply with federal and state regulations and applicable standards intended to prevent communicable disease transmission. Although we and our suppliers have strict quality controls over the procurement and processing of our tissue:

- we can provide no assurance that these quality controls will be adequate;
- we or our suppliers may fail to comply with such regulations and standards;
- even with compliance, our products might nevertheless be viewed by the public as being associated with transmission of disease; and
- a patient that contracts an infectious disease might assert that the use of our products resulted in disease transmission, even if the patient became infected through another source.

Any actual or alleged transmission of communicable disease could result in patient claims, litigation, distraction of

management's attention and potentially increased expenses. Further, any failure in screening, whether by us or other manufacturers of similar products, could adversely affect our reputation, the support we receive from the medical community and overall demand for our products. As a result, such actions or claims, whether or not directed at us, could have a material adverse effect on our reputation with our customers and our ability to distribute our products, which could have a material adverse effect on our business, financial condition and results of operations.

Ethical, legal, and other concerns surrounding the use of human tissue may negatively affect public perception of us or our products, or may result in increased scrutiny of our products and product candidates from a regulatory approval perspective, thereby reducing demand for our products, restricting our ability to market our products or adversely affecting the market price for our common stock.

The commercial success of our products depends in part on general public acceptance of the use of human tissue as a part of the treatment of human diseases and other conditions. The use of human tissue including placental tissue from full‑term normal pregnancies, which is discarded otherwise, has been the subject of debate regarding related ethical, legal and social issues. We do not use embryonic stem cells or fetal tissue, but the public may fail to differentiate our use of adult tissue, including placental tissue from the use by others of embryonic stem cells or fetal tissue. Ethical concerns have been raised by some about the use of donated human tissue in a for‑profit setting. This could result in a negative perception of our company or our products.

Future adverse events in the field of cellular‑based therapy or changes in public policy could also result in greater governmental regulation of our products and potential regulatory uncertainty or delay relating to any required testing or approval.

Our dependence upon human tissue necessary to produce our products may impact our ability to produce these products on a large scale.

As an accredited and licensed tissue bank, we acquire some of our tissue supply through our own collection efforts. The remaining portion of our tissue supply is obtained through third‑party donor agencies. We and our supplier agencies may not be able to collect sufficient amounts of tissue to meet the demand. Shortages or disruptions in the supply of human tissue can adversely impact our ability to fulfill orders, resulting in decreased sales. For example, in 2016, the FDA issued guidance regarding the Zika virus, which limited our supply of placental tissue for a period of time. Since 2016, we have added additional donor agencies and initiated our own collection efforts. Nevertheless, there can be no assurance that any change in guidance from the FDA or future outbreaks of Zika would not hamper our ability to acquire human placental tissue to meet our manufacturing needs.

The availability of donated tissue could also be adversely impacted by public opinion of the donor process as well as our own reputation in the industry. Moreover, the use of human tissue as a part of the treatment for human disease and medical conditions has increased over recent years and continues to increase, creating greater and continually increasing competition and demand for donated human tissue. Even if we are successful in our efforts to expand our compliment of products, we may not be able to secure quantities of human tissue sufficient to meet the demand.

We may not be able to process our products in sufficient quantities to meet market demand or expand our market for the products.

We currently manufacture all of our supply of Grafix and Stravix products at our facility in Columbia, Maryland. Currently, we outsource manufacturing of all of our supply of BIO4 and Cartiform to Aziyo and CTS. A lengthy disruption or shutdown of, or a shortage of supply at, our current manufacturing facilities or the manufacturing facilities of Aziyo or CTS, whether due to the occurrence of natural disasters, the need to comply with the requirements of directives from government agencies, such as the FDA, the lack of supply of human tissue, or otherwise, could have a material adverse effect on our business, financial condition and results of operations.

In addition, our product supply chain and manufacturing infrastructure depends on the performance of a number of complex contracts between us on the one hand and our suppliers on the other. If any of our suppliers, contract manufacturers or other service providers cannot or do not perform their contractual obligations, then our production efforts may suffer. If we cannot or do not perform our contractual obligations, then we may be subject to arbitration, mediation or litigation that could have a material adverse effect on us.

Reliance on third parties entails risks to which we would not be subject if we manufactured all of our products and product components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

We use or may use third parties to help us develop, manufacture, market, and/or distribute our products, and our business may be impaired if our third‑party relationships are unsuccessful.

We have arrangements in place with third parties that help us with certain aspects of our business. Each third party supports us in differing capacities, including our R&D, human tissue supply, regulatory compliance, tissue procurement, manufacturing, testing, or marketing and distribution efforts. We are subject to a number of risks associated with our dependence upon our third‑party relationships, including:

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- the third parties may not cooperate with us or perform their obligations under our agreements with them;
- we cannot control the quality, amount and timing of the third parties' resources that will be devoted to performing their responsibilities under our agreements with them, and they may choose to pursue alternative technologies in preference to those being developed or commercialized with us;
- the third parties may refuse or fail to perform their responsibilities in a timely manner, including breach;
- a third party may terminate its agreement with us for reasons outside our control, and in some cases on limited notice;
- business combinations and changes in a third party's business strategy may adversely affect the third party's willingness or ability to complete its obligations;
- loss of significant rights to the other party if we fail to meet our obligations under our agreements;
- the ability of a third party to successfully market and promote our products;
- withdrawal of support by the third party following development or acquisition by the third party of competing products; and
- disagreements with a third party regarding our agreement with such third party or ownership of intellectual property or other proprietary rights.

Due to these factors and other possible events, we could suffer delays or experience additional costs in the research, development, supply, manufacture, distribution or sale of our products or we may become involved in litigation or arbitration, which would be time consuming and expensive.

We also rely upon third parties for services and raw materials needed for the manufacture and testing of our products.

In order to produce our products, we require biological media, reagents and other highly specialized materials. This is in addition to the human tissue donations used to manufacture our products. These items must be manufactured and supplied to us in sufficient quantities and in compliance with FDA cGTP regulations. To meet these requirements, we either order from or have entered into supply agreements with firms that manufacture these components to cGTP standards and testing service agreements to perform the necessary quality testing.

We rely on third-party suppliers, contract manufacturers and service providers and commodity markets to secure raw materials, parts, components and sub-assembly systems used in our products or to manufacture our products, which expose us to volatility in the prices and availability of these materials. Some of these suppliers or their sub-suppliers are limited or sole-source suppliers. Some of these suppliers or their sub-suppliers are located outside of the United States. A disruption in deliveries from our third-party suppliers, capacity constraints, production disruptions, price increases, or decreased availability of raw materials or commodities, including as a result of catastrophic events, could have an adverse effect on our ability to meet our commitments to customers or increase our operating costs.

Quality and sourcing issues experienced by third-party suppliers can also adversely affect the quality of our products and result in liability and reputational harm.

The purchase of components and products from international sources subjects us to extensive U.S. and foreign governmental trade, import, export and customs regulations and laws. If we, our product candidates, or the manufacturing facilities for our product candidates or components, fail to comply with applicable regulatory requirements, a regulatory agency may seize or detain products or refuse to permit the import of products.

Our most significant third-party arrangement is an exclusive agreement with a subsidiary of Stryker for the distribution of BIO4, and our success with this product depends upon the success of this relationship.

We are party to an exclusive service agreement with Stryker for the commercialization of our viable bone matrix allograft under the name BIO4. Pursuant to the agreement, Stryker is the exclusive worldwide marketer and distributor of allograft services for BIO4 for use in surgical applications, including spine, trauma, extremity, cranial and foot and ankle surgery. This agreement is subject to all of the risks and uncertainties applicable to third-party arrangements generally, including those described above.

The agreement with Stryker provided for an initial four-year exclusive term, which commenced in 2015. In February 2019, Stryker extended the exclusive period for an additional four years. We received an exclusivity fee of $3.9 million in February 2019 to extend the initial term. The agreement provides that Stryker has the option to further extend the term on an exclusive basis for two more years. Pursuant to its terms, Stryker has limited rights to terminate the agreement early. The success of this agreement for us will in part depend upon Stryker's success in marketing and promoting BIO4.

Stryker has significantly greater resources than we do, and this agreement is not as core to its business as it is to ours. We rely upon Stryker's continued performance under this agreement, and any determination by Stryker not to proceed or perform, or any material adverse event that affects Stryker's ability or desire to perform may have a material adverse effect on our business.

We may also enter into additional third-party agreements in the future. If we fail to maintain our existing or any future relationships for any reason, we would need to undertake on our own and at our own expense, or find other third parties, to

perform the activities we currently anticipate will be performed by third parties. This may substantially increase our cash requirements. We may not have the capability or financial capacity to undertake these activities on our own, or we may not be able to enter third‑party relationships on acceptable terms, or at all. This may limit the programs we can pursue and result in significant delays in the development, sale and manufacture of our products, and may have a material adverse effect on our business.

We distribute products through distribution arrangements that sometimes involve the consignment of inventory to third parties, which results in additional risk and uncertainty as to the viability of consigned inventory, inventory accounting, and tax consequences.

We have historically distributed our products either ourselves or through qualified third‑party distributors. In some situations, we store consigned inventory on site in freezers at end‑use hospital or clinic facilities. We commercialize Grafix and Stravix through the efforts of our own direct distribution and marketing staff, as well as through a network of specialty distributors for certain target markets. BIO4 is sometimes commercialized through a consignment arrangement, and our agreement with Stryker and the end users includes consignment terms, as does our agreement with Arthrex and the end users for Cartiform.

Inventory management, revenue recognition, and inventory and receivables accounting are complicated by a consignment arrangement. Because our cryopreserved consigned inventory must be stored at −80 degrees Celsius, it is at risk of thawing, resulting in the total loss of that inventory, which risk of loss is borne by us. From the revenue recognition perspective, no revenue is recognized upon the placement of inventory into consignment, as we retain title and maintain the inventory on our balance sheet. For these products, revenue is recognized when we receive appropriate notification that the product has been used in a surgical procedure. The Restatement corrected, among other things, errors in our prior revenue recognition related to various distributor agreements, including several with consigned inventory. If we are unable to track and maintain proper controls related to consigned inventory, we could experience difficulty in accurately managing and accounting for these consignment arrangements and any related tax implications.

We monitor and verify the condition and status of all consigned inventory on at least an annual basis at our expense. We have increased the controls related to consigned inventory, which has increased our operating expenses, and we will likely incur additional expenses in connection with our future planned improvements in our controls related to consigned inventory. In addition, the FDA's, The American Association of Tissue Banks' and other accrediting agencies' rules, regulations or standards require that we monitor our consigned inventory, and require tracking of human tissue and inventory as it moves through the supply chain.

Moreover, should the FDA or any other regulatory authority determine that we are unable for any reason to continue to distribute consigned inventory, either on account of the viability of that inventory or because of the withdrawal of necessary approvals or other qualifications allowing for the distribution and sale of that inventory, the value of that inventory may have to be completely written off and our balance sheet adjusted accordingly. The complexity of our inventory management, or the application of rules, regulations and standards to our product inventory, or the occurrence of any of these negative events, could have an adverse effect on our business, financial condition and results of operations.

We have no control over whether third parties with whom we contract can comply with applicable regulatory requirements.

Our raw material suppliers, contract manufacturers and distributors, and other third parties that we contract with are subject to many or all of the risks and uncertainties to which we are subject. Similar to us, they are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with applicable regulations and other governmental regulations and corresponding foreign standards. However, we do not control compliance with these regulations and standards by our suppliers, distributors and other third parties with which we contract. They might not be able to comply with these regulatory requirements. If they fail to comply with applicable regulations, the FDA or other regulatory authorities could issue orders of retention, recall, destruction or cessation of manufacturing, or impose sanctions on us, including fines, injunctions, civil penalties, denial of any required marketing approval, delays, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operating restrictions and criminal prosecutions. Any of these actions could significantly and adversely affect the supply and distribution of our products and could have a material adverse effect on our business, financial condition and results of operations.

In addition to costs incurred in product development and management of the reimbursement processes, we will incur additional operating expenses in connection with the expansion of our business.

We expect to continue to incur significant operating expenses in connection with our planned expansion of our business as we seek to:

- continue to develop, expand and support our distribution network of third‑party distributors and independent sales professionals for the distribution of Grafix, BIO4, Cartiform and other products;
- continue to expand and support our internal sales force and marketing capabilities, through the hiring of sales and marketing professionals and building an internal sales and marketing organization;
- hire or engage additional manufacturing, quality control, quality assurance and management personnel as necessary to expand our manufacturing operations;
- expand our manufacturing capacity for our products, all of which must be manufactured in a FDA compliant and validated product manufacturing facility; and
- expand and protect our intellectual property portfolio for our products.

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Our ability to scale up our production capabilities for larger quantities of these products remains to be proven. Our costs in marketing and distributing these products will also increase as production increases.

Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all.

Continued expansion of our business will be expensive and we may seek funds from public and private stock offerings, borrowings under future credit facilities or other sources. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;
- the costs associated with the Restatement and the resolution of related legal proceedings;
- the expenses we incur in manufacturing and managing the supply chain for our products;
- the costs of developing and commercializing new products or technologies;
- the cost of maintaining current products as 361 HCT/Ps or obtaining regulatory approval through the BLA regulatory pathway if any of our products lose their 361 HCT/P status;
- the number and timing of any acquisitions and other strategic transactions;
- the costs associated with capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these factors, we may seek to raise capital, and such capital may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise capital, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressure, changes in our supplier relationships, or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material adverse effect on our business, financial condition and results of operations.

If our manufacturing and storage facility is damaged or destroyed, our business and prospects would be negatively affected.

If our manufacturing and storage facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored product, raw and other materials and work in process.

We lease 61,203 square feet of space in Columbia, Maryland that houses essentially all of our operations. Currently, we maintain insurance coverage totaling $21.25 million against damage to our property and equipment, an additional $15.0 million to cover business interruption and extra expenses, including R&D restoration expenses. If we have underestimated our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies.

The use of our products in human subjects may expose us to product liability claims, and we may not be able to obtain adequate insurance.

We face an inherent risk of product liability claims and only have limited safety data for our products. We derive the raw materials for our products from human donor sources, the production process is complex and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage, or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Whether or not we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among other things:

- significant awards against us;
- substantial litigation costs;
- recall of the product;
- injury to our reputation; or
- adverse regulatory action.

Any of these results could have a material adverse effect on our business, financial condition and results of operations.

We may implement a product recall or voluntary market withdrawal, which could significantly increase our costs, damage our reputation and disrupt our business.

The manufacturing and marketing of our tissue products involve an inherent risk that our tissue products or processes do not

meet applicable quality standards and requirements. In that event, we may voluntarily implement a recall, report a HCT/P deviation or market withdrawal or may be required to do so by a regulatory authority. A recall or market withdrawal of one of our products would be costly and would divert management resources. A recall, HCT/P deviation or market withdrawal regarding one of our products, or a similar product manufactured by another entity, also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety.

We and our distributor sales representatives must comply with U.S. federal and state fraud and abuse laws, including anti-kickback and false claims laws and equivalent foreign rules.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors or third-party distributors may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data, other commercial or regulatory laws or requirements and equivalent foreign rules. We have policies and procedures intended to prohibit and deter such conduct, including a Code of Ethics for Interactions with Healthcare Professionals, a Code of Conduct, and a Whistleblower Policy. However, it is not always possible to identify and deter misconduct by our employees and third parties. Our precautions to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. These laws are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Our and our distributor's relationships with physicians, other healthcare professionals and hospitals are subject to scrutiny under these laws. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs. There can be both criminal and civil penalties for violations;
- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement to induce a false claim payment. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government;
- HIPAA, which created federal criminal laws that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third-party payors;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually (with certain exceptions) to CMS information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners;
- the federal Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business; and
- analogous state and foreign law equivalents of each of the above federal laws, such as:
- anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; or
- state laws that require biologic and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violations of any of the laws described above or any other governmental regulations are punishable by significant civil, criminal and administrative penalties, damages, fines and exclusion from government-funded healthcare programs, such as Medicare and Medicaid. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities.

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If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted.

A significant portion of our revenues and accounts receivable come from government accounts.

We have significant sales to the federal government (whether we are selling our products directly to government accounts or through our current distributors). Any disruption of our products on the Federal Supply Schedule or a change in the way the federal government purchases products like ours, or the price it is willing to pay for our products, could materially and adversely affect our business, results of operations and financial condition.

Changes in internal purchasing procedures by the VA may have an adverse effect on our ability to sell our products to VA hospitals and may have a material adverse effect on our sales and results of operations.

Prior to December 2018, the VA required internal pre-authorization by a warranted contracting officer for purchases of certain types of products, including Grafix and Stravix, for greater than $10,000, except for VA owned inventory or a consignment agreement negotiated by a VA contracting officer. On December 1st, 2018, the VA made changes to the pre- authorization requirement that do not require written documentation, but a pre-authorization would still be needed for input of orders into the VA system. The VA also made adjustments to purchase limits. The impact of these recent changes is still unclear, and thus far the changes and new purchase limits varies across all VA facilities. In the past, pre-authorization delays the purchase of our products. In addition, a pre-authorized product may only be used for the patient for whom authorization was granted. If such product is not used for the authorized patient, it may not be used for any other patient and the product must be returned. The impact and implementation of recent changes to the pre-authorization and purchase limit requirements are still unclear and could have an adverse effect on our ability to sell products to one more VA facilities. Furthermore, any other changes in purchasing procedures and policies by the VA could have an adverse effect on our ability to sell our products to VA hospitals.

The ongoing cost‑containment efforts of GPOs and integrated delivery networks ("IDNs") may have a material adverse effect on our results of operations.

Many customers for our products use GPOs or are members of IDNs in an effort to contain costs. GPOs and IDNs negotiate pricing arrangements with medical supply manufacturers and distributors, which negotiated prices are made available to a GPO's or IDN's affiliated hospitals and other members. If we are not one of the providers selected by a GPO or IDN, affiliated hospitals and other members may be less likely to purchase our products, and, if the GPO or IDN has negotiated a strict compliance contract for another manufacturer's products, we may be precluded from making sales to members of the GPO or IDN for the duration of the contractual arrangement. Our failure to respond to the cost‑containment efforts of GPOs and IDNs may cause us to lose market share to our competitors and could have a material adverse effect on our sales and results of operations.

Significant disruptions of information technology systems or breaches of information security could adversely affect our business.

We rely to a large extent upon information technology systems to operate our business. We collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). We also have outsourced significant elements of our operations to third parties, including vital components of our information technology infrastructure. As a result, many third‑party vendors may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third‑party vendors (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever‑increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. Our efforts to prevent service interruptions or security breaches may not be sufficient. Any interruption or breach in our systems could result in the loss of critical or sensitive confidential information or intellectual property, allow third parties to gain material, inside information that they could use to trade our securities, and could result in financial, legal, business, operational and reputational harm to us.

We may expand our business through acquisitions, licenses, investments and other commercial arrangements in other companies or technologies, which contain significant risks.

We periodically evaluate strategic opportunities to acquire companies, divisions, technologies, products and rights through licenses, distribution agreements, investments or outright acquisitions to grow our business. In connection with one or more of those transactions, we may:

- issue additional equity securities that would dilute our stockholders' value;
- use cash that we may need in the future to operate our business;
- incur debt that could have terms unfavorable to us or that we might be unable to repay;
- structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step‑up in the tax basis for the assets acquired;
- be unable to realize the anticipated benefits, such as increased revenues, cost savings or synergies from additional sales;
- be unable to secure the services of key employees related to the acquisition; and

- be unable to succeed in the marketplace with the acquisition.

Any of these items could materially and adversely affect our revenues, financial condition and profitability. Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Incurring unknown liabilities or the failure to realize the anticipated benefits of an acquisition could materially and adversely affect our business if we are unable to recover our initial investment. Inability to recover our investment, or any write off of such investment, associated goodwill or assets, could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulatory Approval and Other Government Regulations

Should the FDA determine that any of our current products do not meet regulatory requirements that permit qualifying human cells, tissues and cellular and tissue-based products to be manufactured, stored, labeled, and distributed without pre-marketing approval, we may be required to stop manufacturing and distributing such products.

The FDA has developed a tiered, risk-based regulatory framework for human cells, tissues and cellular and tissue-based products, or so-called 361 HCT/Ps (meaning that they comply with section 361 of the Public Health Service Act and with 21 CFR Part 1271). The framework includes criteria for facility management, quality assurance, donor selection and manufacture of 361 HCT/Ps. We believe that Grafix, Stravix, BIO4 and Cartiform meet the regulatory definition of 361 HCT/P products and as a result do not require the FDA's pre-marketing approval. Specifically, we believe all of our current products:

- are minimally manipulated;
- are intended for homologous use only, as reflected in our labeling, advertising, and all other indications of our objective intent (e.g., that Grafix be used only as a wound cover, that Stravix be used only as a surgical cover, that BIO4 be used only for augmentation of bone defects, and that Cartiform be used only as an osteochondral allograft);
- are not combined with another article except for water, crystalloids, or a sterilizing, preserving or storage agent in a manner that raises no new clinical safety concerns; and
- do not have a systemic effect and are not dependent on the metabolic activity of living cells for their primary function.

These criteria form the framework governing our advertising and promotional activities. If we advertise or promote any product in a manner that conveys an intent that it be used for non-homologous uses, that suggests that the product's primary function depends on systemic effects or the metabolic activity of living cells, or that indicates that our manufacturing process manipulates the product more than minimally by altering the original relevant characteristics of the tissue relating to its utility for reconstruction, repair, or replacement, we will risk causing our products to no longer qualify as 361 HCT/Ps.

On September 26, 2013, we received the Untitled Letter from the FDA. The agency uses untitled letters to communicate violations that the FDA does not consider of regulatory significance sufficient to lead to an enforcement action. The Untitled Letter stated that Grafix and Ovation did not meet the definition of a 361 HCT/P. Among the grounds for the FDA's position were our marketing claims, including wound healing claims for Grafix. Specifically, the Untitled Letter indicated that Grafix did not meet the requirements because it is dependent upon the metabolic activity of living cells for its primary function and is not intended for autologous use or allogeneic use in a first or second degree relative. On September 30, 2013, we provided clarifying information to the FDA addressing these concerns. Specifically, we communicated that while Grafix does retain the natural cell population, it is not enriched or expanded in any way; instead, the tissue is preserved so that it closely resembles the source tissue in its native state in accordance with the FDA's definition of minimal manipulation.

In order to make our marketing claims for Grafix clearer, we committed to the FDA to update our labeling and marketing materials for Grafix to that of a wound cover. By October 2014, we completed all commitments made to the FDA, including the discontinuance of Ovation. In April 2016, the FDA performed a routine inspection of us, which included follow-up on the actions taken to address the Untitled Letter. In May 2016, we received a FDA Establishment Inspection Report which stated that there were no observations, findings, warnings or untitled letters for either the routine inspection or the Untitled Letter follow-up.

In March 2017, we completed the development of Prestige Lyotechnology as an alternative to cryopreservation, which previously had been the only method available for long-term preservation of living cells and tissues, and which we are using to process our current products. We designed our new technology to preserve living cells within tissues while stored at room temperatures. We have used Prestige Lyotechnology and completed and launched GrafixPL PRIME. We intend to use Prestige Lyotechnology in developing additional placental products. We believe that any additional products based on Prestige Lyotechnology will comply with the above requirements for 361 HCT/Ps.

We engage in ongoing communication with FDA representatives regarding the applicable regulatory requirements and pathways for our products and product candidates. Determining whether a product complies with these regulatory requirements and pathways is complex and dependent upon numerous factors and subject to varying interpretations and conclusions. In November 2017, the FDA finalized its Guidance Document entitled "Regulatory Considerations for Human Cell, Tissues, and Cellular Tissue-Based Products: Minimal Manipulation and Homologous Use" and issued a corrected version of this document in December 2017. This document provides the FDA's current guidance on 361 HCT/Ps. Specifically, it clarifies the FDA's definitions of minimal

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manipulation and homologous use. The FDA has given affected companies until November 2020 to determine if they meet the requirements and, if not, to file an IND.

We believe all of our current products (Grafix, GrafixPL, Stravix, BIO4 and Cartiform), as well as our products being developed using our Prestige Lyotechnology, meet, or will meet, the FDA's current interpretations. However, the FDA may not agree with our views on these matters. Should the FDA decide that our current and future products do not meet the regulatory definition of 361 HCT/Ps, we will not be able to produce and distribute these products unless and until we submit a BLA and obtain pre-marketing approval from the FDA, which would require clinical trials and could take years to obtain, at significant expense. This or any other determination by the FDA that adversely affects our ability to produce or to market any of our products or product candidates would have a material adverse effect on our business, financial condition and results of operations.

Our business is subject to an inherently uncertain and evolving area of regulation.

The regulatory framework that the FDA has developed for 361 HCT/Ps is inherently uncertain and the FDA's regulation of 361 HCT/Ps is evolving. The FDA may alter or recalibrate its regulatory interpretations and enforcement activities, including in the event a competitor obtains pre-marketing approval for a product similar to any of our products. Further, the FDA could require that our products, which lack pre-marketing approval by the FDA, be taken off the market.

In addition, while the FDA's advertising and promotional labeling regulations do not apply to 361 HCT/Ps, the agency could become more exacting with regard to acceptable advertising and promotional activities for 361 HCT/Ps. Specifically, under FDA regulations, a manufacturer may not promote a 361 HCT/P in a manner that communicates an objective intent of the manufacturer for the HCT/P to be used for non-homologous uses. In addition, a manufacturer risks undermining its product's 361 status if it describes its product in a way that suggests that the product does not otherwise meet the criteria for qualifying as a 361 HCT/P, such as by emphasizing the metabolic activity of live cells in the product. Because various government agencies that regulate HCT/Ps, such as the FDA and CMS, employ different terms to describe HCT/Ps and apply different criteria to its decisions, a risk exists that our sales representatives and other employees may use terms applicable to one regulatory regime that are detrimental in another regulatory regime. An example would be that describing an HCT/P as treating a wound for purposes of justifying reimbursement could be interpreted by the FDA as implying that the manufacturer intends the product to be used for non-homologous wound healing.

If the FDA determines that any of our current products are not 361 HCT/Ps, or that any of our future products are not 361 HCT/Ps, we will be required to seek and obtain pre-marketing regulatory approval.

If the FDA determines that one or more of our current products do not meet the criteria for 361 HCT/Ps, we will need to pursue pre-marketing approval applicable to biologics in the United States, which is also referred to as licensure. We are currently considering product candidates that require licensure from the FDA. In the United States, a company must complete rigorous preclinical testing and extensive clinical trials that demonstrate the safety, purity and potency of a biological product in order to apply for licensure to market the product. The steps generally required by the FDA include:

- performance of preclinical (animal and laboratory) tests, in accordance with the FDA's cGLP regulations and other applicable requirements;
- submissions to the FDA of an IND, which must become effective before clinical trials may commence;
- approval by an independent IRB of each clinical site before a clinical trial is initiated;
- performance of adequate and well-controlled clinical trials according to the FDA's cGCP regulations, and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity and potency of the investigational biological product in the intended target population for its intended use;
- establishment and validation of a consistent and reproducible manufacturing process intended for commercial use, including the collection of appropriate manufacturing data;
- preparation and submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of a FDA inspection of the manufacturing facility or facilities where the biological product candidate is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the biological product candidate's identity, safety, strength, quality, potency, and purity;
- potential FDA inspection of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA before any commercial sale or shipment of the product can begin again.

The processes are expensive and can take many years to complete. If we are required to obtain pre-marketing approval from the FDA for any of our existing or future products, we may not be able to demonstrate the safety, purity and potency of our products to the satisfaction of regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are out of our control. Safety concerns may emerge that could lengthen the ongoing clinical trials or require additional clinical trials to be conducted. Promising results in early clinical trials may not be replicated in subsequent clinical trials. Regulatory authorities may also require additional testing, and we may be required to demonstrate that

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our products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical trials. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved products may not be approved, which could limit our revenue opportunities.

Our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and our failure to comply could result in negative effects on our business.

As discussed above, the FDA has specific regulations governing our tissue-based products, or HCT/Ps. The FDA's regulation of HCT/Ps includes requirements for registration and listing of products, donor screening and testing, manufacture and distribution, labeling, record keeping and adverse-reaction reporting, and inspection and enforcement. The FDA has broad regulatory and enforcement powers.

If we fail to comply with the FDA regulations regarding our tissue-based products, the FDA could take enforcement action, including, without limitation, any of the following sanctions that may be relevant to our current or future business operations, and the manufacture of our products or processing of our tissue could be delayed or terminated:

- untitled letters and warning letters;
- orders of retention, recall, destruction and cessation of manufacturing;
- product seizures, injunctions and civil penalties;
- operating restrictions;
- refusing applications for licensure of new products;
- suspending current applications for licensure, or revoking or suspending licenses already granted;
- refusal to allow the importation of our products or raw materials; and
- criminal prosecution.

It is likely that the FDA's regulation of HCT/Ps will continue to evolve in the future. Complying with any such new regulatory requirements may entail significant time delays and expense, which could have a material adverse effect on our business, financial condition and results of operation.

In addition to FDA regulations, we are subject to other laws, rules, regulations, and standards regarding the use of human tissue.

We are registered with the FDA as a tissue bank. In addition, some states have their own tissue banking regulations. We are licensed as a tissue bank in Maryland, California, Florida, Illinois, Oregon, Delaware and New York. If we fail to comply with any of the requirements for licensure as a tissue bank, we will not be able to operate as a tissue bank and collect and store donor tissue. The loss of this licensure could adversely impact the quantity of human tissue available to us and our ability to process our products, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, procurement of certain human organs and tissues for transplantation is subject to the restrictions of NOTA, which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks, hospitals and physicians for their services associated with the recovery, storage and transportation of donated human tissue. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our business, financial condition and results of operations.

Our business involves the use of hazardous materials that could expose us to environmental and other liability.

We have facilities in Maryland that are subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our R&D and manufacturing activities. These laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. We cannot assure you that accidental contamination or injury to our employees and third parties from hazardous materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

Federal and state laws that protect the privacy and security of personal information may increase our costs and limit our ability to collect and use that information and subject us to liability if we are unable to fully comply with such laws.

Numerous federal and state laws, rules and regulations govern the collection, dissemination, use, security and confidentiality of personal information, including individually identifiable health information. These laws include:

- provisions of HIPAA that limit how covered entities and business associates may use and disclose PHI, provide certain rights to individuals with respect to that information and impose certain security requirements;

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- HITECH, which strengthens and expands the HIPAA Privacy Rule and Security Rules and imposes data breach notification obligations;
- other federal and state laws restricting the use and protecting the privacy and security of personal information, including health information, many of which are not preempted by HIPAA;
- federal and state consumer protection laws; and
- federal and state laws regulating the conduct of research with human subjects.

As part of our business operations, including our medical record keeping, third‑party billing and reimbursement and R&D activities, we collect and maintain PHI in paper and electronic format. Standards related to health information, whether implemented pursuant to HIPAA, HITECH, state laws, federal or state action or otherwise, could have a significant effect on the manner in which we handle personal information, including healthcare‑related data, and communicate with payors, providers, patients, donors and others, and compliance with these standards could impose significant costs on us or limit our ability to offer services, thereby negatively impacting the business opportunities available to us.

If we are alleged to not comply with existing or new laws, rules and regulations related to personal information we could be subject to litigation and to sanctions that include monetary fines, civil or administrative penalties, civil damage awards or criminal penalties.

We face significant uncertainty in the industry due to government healthcare reform.

There have been and continue to be proposals by the federal government, state governments, regulators and third‑party payors to control healthcare costs, and generally, to reform the healthcare system in the United States. With the Trump Administration and the 115th Congress, there have been certain regulatory and legislative changes to the Patient Protection and Affordable Care Act (the "Affordable Care Act"). For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible. However, it remains unclear how any new regulations or legislation might affect the prices we may obtain for any of our products. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may harm our business and prevent us from being able to attain and maintain profitability. We also cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us.

Risks Related to Intellectual Property

Given our limited patent position in regard to our products, if we are unable to protect the confidentiality of our proprietary information and know‑how related to these products, our competitive position would be impaired and our business, financial condition, and results of operations could be adversely affected.

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection and operate without infringing on the patented rights of third parties. Our policy is to file patent applications to protect technologies and products that we consider important to our business and operations. We hold an ownership interest in a number of patents issued and applications in the United States, Canada, certain countries of the European Union and a few other foreign countries.

It is possible that we will need to defend patents from challenges by others from time to time. Certain of our U.S. patents may be challenged by others in a post-grant proceeding under the America Invents Act of 2011. A post‑grant proceeding has become increasingly common in the United States and is costly to defend. Our patented rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

A significant amount of our technology, including our information regarding the manufacturing process for our products, is patent pending, unpatented or is maintained by us as trade secrets or confidential know‑how. In an effort to protect this proprietary information, we require our employees, consultants, service providers, advisors and other third parties to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or entity or made known to the individual or entity by us during the individual's or entity's relationship with us be kept confidential and not disclosed to third parties without prior written consent by us. These agreements, however, may not provide us with adequate protection against improper use or disclosure of trade secrets or confidential information, and these agreements may be breached. For example, a portion of the manufacturing methodology and know‑how for Grafix is protected by trade secret or through confidentiality arrangements. A breach of confidentiality could affect our competitive position. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or know‑how.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets or know‑how could impair our competitive position and could have a material adverse effect on our

business, financial condition and results of operations.

If our patent position does not adequately protect our products, others could compete against us more directly, which would harm our business and have a material adverse effect on our business, financial condition, and results of operations.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit. Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to, when appropriate, file product and process applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. A portion of our technology, including certain know-how regarding the production processes for our products, is unpatented and is maintained by us as trade secrets. The lack of patent protection for our products reduces the barrier for entry by others and makes these products susceptible to increased competition, which could be harmful to our business.

If we infringe or are alleged to infringe on intellectual property rights of third parties, it could adversely affect our business, financial condition, and results of operations.

Our research, development and commercialization activities, and the manufacture or distribution of our products, may infringe or be alleged to infringe patents owned by third parties and to which we do not hold licenses or other rights. There may be patent applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be enjoined from certain activities including a stop or delay in research, development, manufacturing or sales activities related to the product or technology that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and, as a result, on our business, financial condition and results of operations.

We may become involved in lawsuits or administrative proceedings to protect or enforce our patents or the patents of our service providers or licensors, which could be expensive and time consuming.

Litigation may be necessary to enforce patents issued or licensed to us, to protect trade secrets or know-how, or to determine the scope and validity of proprietary rights. Litigation, post-grant review, reexamination, opposition or interference proceedings could result in substantial additional costs and diversion of management focus. If we are ultimately unable to protect our technology, trade secrets or know-how, we may be unable to operate profitably.

Competitors may infringe on our patents or the patents of our service providers or licensors. As a result, we may be required to file infringement claims to protect our proprietary rights. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. Interference proceedings brought by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our service providers or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our service providers and licensors, to prevent misappropriation of our proprietary rights.

Furthermore, though we would seek protective orders where appropriate, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Annex I (unaudited)
Risk factors of Osiris Therapeutics as per the Osiris Therapeutics annual report 2018

The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed if the patents were infringed or misappropriated.

We have obtained licenses from third parties for patents and patent application rights, allowing us to use intellectual property rights owned by or licensed to these third parties. We do not control the maintenance, prosecution, enforcement or strategy for many of these patents or patent application rights and as such are dependent in part on the owners of the intellectual property rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit these technologies.

Risks Related to Our Common Stock

Our common stock was delisted from trading on NASDAQ and relisted on August 1, 2018, which we expect to continue to have a material effect on us and our stockholders.

We were delinquent in the filing of our Annual Reports on Form 10-K for the years ended December 31, 2015 and December 31, 2016, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016, September 30, 2016, March 31, 2017, June 30, 2017 and September 30, 2017. NASDAQ formally delisted our common stock on April 28, 2017 as a result of our failure to timely file our SEC reports. Following the filing of our Comprehensive Form 10- K on March 28, 2018, we applied for relisting to the NASDAQ, which was granted on August 1, 2018. This gap in our listing may adversely affect our common stock share price.

The trading price of the shares of our common stock is highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- reduced access to a trading market for our common stock as a result of our delisting from NASDAQ;
- loss of investor confidence in us due to the Restatement;
- the recent changes in our senior management team and departures of other key personnel over the last few years;
- the marketing and distribution of new products by our competitors;
- regulatory developments in the United States, generally or specific to us and our products;
- changes in the structure of healthcare payment systems;
- expiration or termination of our significant relationships with third parties;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- sales of substantial amounts of our stock by existing stockholders;
- sales of our stock by insiders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- general economic, industry and market conditions;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- commercial, stockholder class action and derivative, intellectual property or product liability litigation against us; and
- the other factors described in this "Risk Factors" section.

We do not intend to pay cash dividends.

We currently do not intend to pay cash dividends for the foreseeable future. We currently intend to retain earnings, if any, to finance our operations and growth. As a result, capital appreciation, if any, of our common stock will be an investor's only source of potential gain from our common stock for the foreseeable future.

Certain provisions of Maryland law and of our charter and bylaws contain provisions that could delay and discourage takeover attempts and any attempts to replace our current directors by stockholders.

Certain provisions of Maryland General Corporation Law ("MGCL") and of our Maryland charter and Maryland bylaws contain provisions that may make it more difficult to or prevent a third party from acquiring control of us or changing our Board and

management. These include, but are not limited to, the following:

- authorization of the board of directors to issue shares of preferred stock generally without stockholder approval;
- requirements that special meetings of stockholders may only be called by stockholders, upon request of stockholders holding at least 20% of the capital stock issued and outstanding; and
- requirements that our stockholders comply with advance notice procedures in order to nominate candidates for election to our Board or to place stockholders' proposals on the agenda for consideration at stockholder meetings.

Maryland law also prohibits "business combinations" between us and an interested stockholder or an affiliate of an interested stockholder for five years after the most recent date on which the interested stockholder becomes an interested stockholder. These business combinations include a merger, consolidation, share exchange or, in certain circumstances specified in the statute, an asset transfer or issuance or reclassification of equity securities. Maryland law defines an interested stockholder as any person who beneficially owns 10% or more of the voting power of the corporation's stock, or an affiliate or associate of the corporation who, at any time within the two-year period prior to the date in question, was the beneficial owner of 10% or more of the voting power of the corporation's then-outstanding voting stock. A person is not an interested stockholder if the board of directors of the corporation approved in advance the transaction by which the person otherwise would have become an interested stockholder. However, such approval may be conditional.

After the five-year prohibition, any business combination between the corporation and an interested stockholder or an affiliate of an interested stockholder generally must be recommended by the board of directors and approved by the affirmative vote of at least 80% of the votes entitled to be cast by holders of the then-outstanding shares of voting stock, and two-thirds of the votes entitled to be cast by holders of the voting stock other than stock held by the interested stockholder with whom or with whose affiliate the business combination is to be effected or stock held by an affiliate or associate of the interested stockholder. These super-majority vote requirements do not apply if the holders of the common stock receive a minimum price, as defined under Maryland law, for their stock in the form of cash or other consideration in the same form as previously paid by the interested stockholder for its stock.

The statute permits various exemptions from its provisions, including business combinations that are approved or exempted by the board of directors before the time that the interested stockholder becomes an interested stockholder. Our Board has not exempted us from the business combination statute. Consequently, unless the Board adopts an exemption from this statute in the future, the statute will be applicable and may affect business combinations between us and other persons. The statute may discourage others from trying to acquire control of us or increase the difficulty of consummating any such acquisition.

Subtitle 8 of Title 3 of the MGCL ("Subtitle 8") permits a Maryland corporation with a class of equity securities registered under the Exchange Act, and with at least three independent directors to elect to be subject to any or all of five provisions:

- a classified board;
- a two-thirds vote requirement to remove a director;
- a requirement that the number of directors be fixed only by the vote of the directors;
- a requirement that a vacancy on the board be filled only by the remaining directors and for the remainder of the full term of the directorship in which the vacancy occurred; and
- a majority requirement for the calling of a special meeting of stockholders.

An eligible Maryland corporation like us can elect into this statute by provision in its charter or bylaws or by a resolution of its board of directors, without stockholder approval. Furthermore, we can elect to be subject to the above provisions regardless of any contrary provisions in the charter or bylaws. Pursuant to Subtitle 8, we have elected to provide that vacancies on our Board may be filled only by the remaining directors and for the remainder of the full term of the class of directors in which the vacancy occurred.

Concentration of ownership of our common stock among our existing executive officers, directors, and principal stockholders may prevent others from influencing significant corporate decisions, and provisions in our charter allowing for a stockholder vote by consent in lieu of a meeting may make it easier for stockholders holding a majority of our common stock to take action.

Our executive officers, directors and beneficial owners of 5% or more of our common stock and their affiliates, in aggregate, beneficially own approximately 52.1% of our outstanding common stock as of February 28, 2018. Included among this 52.1%, Peter Friedli, the Chairman of the Board, and certain entities with which he is affiliated, beneficially own approximately 42.9% of our outstanding common stock as of February 28, 2019. These persons, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with our interests or the interests of other stockholders.

Moreover, as permitted by the MGCL, our charter provides that the holders of common stock entitled to vote generally in the election of directors may take action or consent to any action by delivering a consent in writing or by electronic transmission of the stockholders entitled to cast not less than the minimum number of votes (which is generally either a majority of votes cast or a majority of votes entitled to be cast) that would be necessary to authorize or take the action at a stockholders meeting if the corporation gives notice of the action not later than ten (10) days after the effective date of the action to each holder of the class of common stock and to each stockholder who, if the action had been taken at a meeting, would have been entitled to notice of the meeting.

Annex I (unaudited)
Risk factors of Osiris Therapeutics as per the Osiris Therapeutics annual report 2018

Accordingly, these persons acting together, and Mr. Friedli specifically, currently has, and will continue to have, a significant influence over the outcome of all corporate actions requiring stockholder approval, including any actions that may be taken by stockholder consent in lieu of a meeting.

Risks Related to the Restatement of Our Financial Statements and Failure to File SEC Reports

We have restated our prior financial statements, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on our stock price.

As a result of the Restatement, we have become subject to a number of additional costs and risks, including costs for accounting and legal fees in connection with or related to the Restatement and the remediation of our material weaknesses in internal control over financial reporting. In addition, the attention of our management team has been diverted by these efforts. The Restatement and related matters could impair our reputation or could cause our counterparties to lose confidence in us. Each of these occurrences could have a material adverse effect on our business, financial condition, results of operations and stock price.

Our management has identified material weaknesses in the Company's internal control over financial reporting which could, if not remediated, result in additional material misstatements in our consolidated financial statements. We may be unable to develop, implement and maintain appropriate controls in future periods.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, and the Sarbanes-Oxley Act of 2002 and SEC rules require that our management report annually on the effectiveness of the Company's internal control over financial reporting. Among other things, our management must conduct an assessment of the Company's internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to audit, the effectiveness of the Company's internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. As disclosed in Part II, Item 9A, "Controls and Procedures" of this Form 10-K, our management, with the participation of our current Chief Executive Officer and our Chief Financial Officer, has determined that we had material weaknesses in the Company's internal control over financial reporting as of December 31, 2018.

A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. We are actively engaged in developing and implementing a remediation plan designed to address such material weaknesses. However, additional material weaknesses in the Company's internal control over financial reporting may be identified in the future. Any failure to implement or maintain required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, or could result in material misstatements in our consolidated financial statements. These misstatements could result in a further restatement of our consolidated financial statements, cause us to fail to meet our reporting obligations, reduce our ability to obtain financing or cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

Although we are working to remedy the ineffectiveness of the Company's internal control over financial reporting, there can be no assurance as to when the remediation plan will be fully developed and implemented. Until our remediation plan is fully implemented, our management will continue to devote significant time, attention and financial resources to these efforts. If we do not complete our remediation in a timely fashion, or at all, or if our remediation plan is inadequate, there will continue to be an increased risk that we will be unable to timely file future periodic reports with the SEC and that our future consolidated financial statements could contain errors that will be undetected. Further and continued determinations that there are material weaknesses in the effectiveness of the Company's internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain and require additional expenditures of both money and our management's time to comply with applicable requirements. For more information relating to the Company's internal control over financial reporting, the material weaknesses that existed as of December 31, 2018 and the remediation activities undertaken by us, see Part II, Item 9A, "Controls and Procedures" of this Form 10-K.

Our failure to prepare and timely file our periodic reports with the SEC limits our access to the public markets to raise debt or equity capital.

We did not file our Annual Reports on Form 10-K for the years ended December 31, 2015 and December 31, 2016 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016, September 30, 2016, March 31, 2017, June 30, 2017 and September 30, 2017 as required by the SEC. Because we did not comply with our reporting requirements with the SEC, we are limited in our ability to access the public markets to raise debt or equity capital. Our limited ability to access the public markets could prevent us from pursuing transactions or implementing business strategies that we might otherwise believe are beneficial to our business. Even if we maintain compliance with our SEC reporting obligations prospectively, until one year from the date we regain and maintain status as a current filer, we will be ineligible to use shorter and less costly filing forms, such as Form S-3, to register our securities for sale. We may use Form S-1 to register a sale of our stock to raise capital or complete acquisitions, but doing so would likely take longer than using a shorter and less costly form, increase transaction costs and adversely impact our ability to raise capital or complete acquisitions of other companies in a timely manner.