

**New Venturetec
Semi-Annual Report
March 31, 2016**

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Disclaimer

New Venturetec 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. No investment in New Venturetec 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 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 shares may be rather illiquid. New Venturetec 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 shares on the market.

Most of the investees are 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 – 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 un-recoverability of an investment. The financial risk management objectives and policy of New Venturetec 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 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 if he can afford the complete loss of the investment without having to change his lifestyle.

Shareholder letter

Dear Shareholders,

It has been a very unfortunate past six month. Due to the restatement of the Osiris financials in terms of revenue recognition, which Osiris announced, the share price dropped. As publicly announced, the revenue recognition relates to the timing of recognition and is related to some distributors in 2014 and 2015. The auditors are still working on it. Osiris has no control over the time to complete. The time to complete is uncertain.

Osiris has also made public, that it has selected Ernst & Young LLP as its independent auditor for 2015 who will start its work on the 2015 audit once the current auditors have completed their work.

I'm very sorry for the current loss in value. Everything is done by the rules. Osiris Therapeutics is committed to complete and report on the financials as soon as possible and acts according to the rules including communication. Management is continuing to focus on building the business.

I'm optimistic, that the current problems will be solved and the company will continue its path in developing and marketing products which benefit patients.

Myriad had a good fourth quarter and is on track for the five year plan as announced.

We are still working on selling Prolexys, so far with little success.

Thank you for your understanding

Your sincerely,

A handwritten signature in cursive script, appearing to read "P. Fin".

Risks

The risk of venture capital investments is 100%

As briefly outlined earlier, New Venturetec 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.

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 start-up 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 accounts of the Company's subsidiary are maintained in US Dollars and the Net Asset Value per share is also 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 consolidated 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, on a consolidated basis, 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 biweekly 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 the annual report of New Venturetec.

Investment advisor

The Company is advised by Madison Investment Advisor, 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 of Venturetec's investment in Osiris Therapeutics

Venturetec, Inc. directly owns 4,103,301 shares of Osiris Therapeutics, which represents 11.9% of the outstanding shares of Osiris Therapeutics. Based on this ownership, Venturetec 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"). Venturetec 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 Venturetec 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 Venturetec 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 the following limitations:

- 1% of the stock outstanding, which for Osiris Therapeutics would be 344,526 shares.
- The average weekly reported volume of trading reported on all national securities exchanges during the preceding four weeks ending September 30, 2015, which for Osiris Therapeutics is currently 934,800.
- The average weekly volume of trading of the securities reported through the consolidated transaction reporting system, which for the week ended September 30, 2015, was 742,100 shares.

Accordingly, for sales of Osiris Therapeutics common stock, the so called "volume limitation" under Rule 144 for an affiliate is currently 934,800 shares available to be sold during the next three months.

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, Venturetec is further limited as to when it can engage in purchasing or selling shares of Osiris Therapeutics. Venturetec 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.

Risks of Osiris Therapeutics

Extracts from Osiris Therapeutics 10k Reporting 2014 regarding specific risk factors of the company shall be studied on Annex I on page 24.

New Venturetec Ltd., Steinhausen

Interim Consolidated Financial Statements
October 1, 2015 to March 31, 2016

Condensed Consolidated Interim Balance Sheet

	Note	March 31, 2016 (unaudited) USD	September 30, 2015 (audited) USD
Assets			
Cash and cash equivalents		3,920,353	4,287,464
Other accounts receivable		1,325,822	1,465,838
Current assets		5,246,175	5,753,302
Venture capital investments and notes receivable	6	31,375,849	83,783,969
Non-current assets		31,375,849	83,783,969
Total assets		36,622,024	89,537,271
Liabilities and equity			
Accrued advisory fees		43,507	175,238
Other accrued expenses		114,353	296,507
Accrued interests on convertible bonds		116,431	424,510
Loans payable to related parties	8.3	6,913,778	6,847,961
Bank loans payable		1,500,752	1,500,740
Current liabilities		8,688,821	9,244,956
Convertible bonds		15,541,121	15,343,365
Deferred tax liabilities		8,088	266,213
Non-current liabilities		15,549,209	15,609,578
Total liabilities		24,238,030	24,854,534
Share capital		20,785,350	20,785,350
Additional paid-in capital		28,784,665	28,784,665
Translation reserve		2,155,549	2,180,861
Conversion options / own equity instruments		168,451	168,451
(Accumulated deficits) / Retained earnings		(39,510,021)	12,763,410
Equity attributable to shareholders of New Venturetec		12,383,994	64,682,737
Total liabilities and equity		36,622,024	89,537,271
Number of shares outstanding		5,000,000	5,000,000
Net asset value per share		2.48	12.94

Condensed Consolidated Interim Statement of Comprehensive Income

	Note	Six months ended March 31, 2016 (unaudited) USD	Six months ended March 31, 2015 (unaudited) USD
Income			
Gains on venture capital investments	6.1/6.2	160,000	20,568,332
Dividend income	6.2	820,660	0
		980,660	20,568,332
Expenses			
Losses on venture capital investments	6.1/6.2	(52,408,120)	(5,327,488)
Advisory fees		(151,875)	(301,301)
Interest on loans from related parties	8.3/8.4	(396,938)	(379,456)
Interest on loans from third parties		(74,020)	(84,863)
General and administrative expenses		(223,158)	(213,562)
Bank charges		(298)	(85)
Net foreign exchange profit / (loss)		(211,714)	378,018
		(53,466,123)	(5,928,737)
(Loss) / Profit before tax		(52,485,463)	14,639,595
Income tax income / (expense)		212,032	(86,806)
(Loss) / Profit for the period attributable to shareholders		(52,273,431)	14,552,789
Other comprehensive income			
Items that are or may be reclassified to profit or loss			
Translation adjustment		(25,312)	37,810
Total items that are or may be reclassified to profit or loss		(25,312)	37,810
Other comprehensive income for the year		(25,312)	37,810
Total comprehensive income for the period attributable to shareholders		(52,298,743)	14,590,599
Weighted average number of shares outstanding during the year (basic)		5,000,000	5,000,000
Earnings per share (basic)	9	(10.45)	2.91
Weighted average number of shares outstanding during the year (diluted)		6,584,737	6,584,737 ¹⁾
Earnings per share (diluted)	9	(7.89)	2.26

¹ Figures have been restated (refer to Note 9).

Condensed Consolidated Interim Statement of Changes in Equity for the six months ended March 31, 2016 and 2015

	Share capital USD	Additional paid-in capital USD	Trans- lation reserve USD	Conversion options / own equity instruments USD	(Accumu- lated deficits) / Retained earnings USD	Total equity attributable to shareholders of New Venturetec USD
Balance as of 01.10.2014	20,785,350	28,784,665	2,134,887	168,451	(2,234,702)	49,638,651
Translation adjustment	0	0	37,810	0	0	37,810
Total other comprehensive income	0	0	37,810	0	0	37,810
Profit for the period	0	0	0	0	14,552,789	14,552,789
Total comprehensive income	0	0	37,810	0	14,552,789	14,590,599
Balance as of 31.03.2015 (unaudited)	20,785,350	28,784,665	2,172,697	168,451	12,318,087	64,229,250
Balance as of 01.10.2015	20,785,350	28,784,665	2,180,861	168,451	12,763,410	64,682,737
Translation adjustment	0	0	(25,312)	0	0	(25,312)
Total other comprehensive income	0	0	(25,312)	0	0	(25,312)
Loss for the period	0	0	0	0	(52,273,431)	(52,273,431)
Total comprehensive income	0	0	(25,312)	0	(52,273,431)	(52,298,743)
Balance as of 31.03.2016 (unaudited)	20,785,350	28,784,665	2,155,549	168,451	(39,510,021)	12,383,994

Condensed Consolidated Interim Cash Flow Statement

		Six months ended March 31, 2016 (unaudited) USD	Six months ended March 31, 2015 (unaudited) USD
	Note		
Advisory fees paid		(283,606)	(225,387)
Payments for general and administrative expenses		(333,791)	(208,638)
Bank charges		(298)	(85)
Cash used in operating activities		(617,695)	(434,110)
Purchase of venture capital investments/notes rec.	6.1/6.2	0	(500,000)
Proceeds on disposal of venture capital investments		307,982	1,085,647
Dividends received (net of tax)		697,561	0
Cash provided by investing activities		1,005,543	585,647
Interest paid		(758,082)	(706,937)
Cash used in financing activities		(758,082)	(706,937)
Exchange effect on cash and cash equivalents		3,123	3,918
Net change in cash and cash equivalents		(367,111)	(551,482)
Cash and cash equivalents at beginning of year		4,287,464	1,196,141
Cash and cash equivalents at end of period		3,920,353	644,659

Basis of the condensed consolidated interim financial statements

1 Principal activities

New Venturetec Ltd., Steinhausen ("the Company", "the Parent 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.

The consolidated financial statements as at and for the six months ended March 31, 2016, include the Company and its wholly-owned subsidiary Venturetec, Inc., Tortola, British Virgin Islands ("the Subsidiary") (together referred to as the "Group"). The Subsidiary was incorporated on September 11, 1996 with a share capital of USD 20 million. As of March 31, 2016, the Company's venture capital investments are held via this subsidiary.

2 Statement of compliance

The Group's consolidated 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. They 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 consolidated financial statements as at and for the year ended September 30, 2015.

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.

New Venturetec Ltd. applies "Investment Entities - Amendments to IFRS 10, IFRS 12 and IAS 27" since October 1, 2013.

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

- New Venturetec holds multiple investments;
- New Venturetec'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.

New Venturetec Ltd. holds, through its wholly-owned subsidiary Venturetec, Inc., multiple investments and ownership interests in the form of redeemable shares. Following the requirements of IFRS 10, New Venturetec Ltd. applies the investment entity exemption. Investments exceeding 50% of the share capital are not consolidated but classified as financial assets at fair value through profit or loss. For further information, refer to note 6 in the disclosures of these consolidated financial statements.

New Venturetec Ltd. consolidates its wholly-owned subsidiary Venturetec, Inc. Venturetec, Inc. provides services that relate to the investment activities and therefore does not meet the requirements for the investment entity exemption. Consequently, Venturetec, Inc. is consolidated. Due to the amendment to IFRS 10 issued in December 2014, the consolidation of Venturetec, Inc. needs to be reconsidered as of October 1, 2016.

Key sources of estimation uncertainty

The determination of fair value for financial assets and liabilities for which there is no observable market price requires the use of valuation techniques as described in note **Fehler! Verweisquelle konnte nicht gefunden werden.** For financial instruments that trade infrequently and have little price transparency, fair value is less objective, and requires varying degrees of judgment depending on liquidity, concentration, uncertainty of market factors, pricing assumptions and other risks affecting the specific instrument. See also note **Fehler! Verweisquelle konnte nicht gefunden werden.**

4 New standards and interpretations issued but not yet adopted

The following new and revised Standards and Interpretations have been issued since publishing the consolidated financial statements for the year ended 30 September 2015, but are not yet effective. They have not been applied early in these (consolidated) financial statements. Their impact on the (consolidated) financial statements of New Venturetec Ltd. has not yet been systematically analysed, unless indicated otherwise.

	Effective date	Planned application by New Venturetec Ltd. in reporting year
New Standards or Interpretations		
IFRS 16: Leases	January 1, 2019	Reporting year 2019/20
Revisions and amendments of Standards and Interpretations		
Recognition of Deferred Tax Assets for Unrealised Losses (Amendment to IAS 12)	January 1, 2017	Reporting year 2017/18
Disclosure Initiative (Amendments to IAS 7)	January 1, 2017	Reporting year 2017/18

5 Summary of significant accounting policies

The accounting policies applied in these interim financial statements are the same as those applied in the Group's consolidated financial statements as at and for the year ended September 30, 2015, with the following amendment:

5.1 Dividend income

Dividend income is recognized in profit or loss on the date the Company's right to receive payments is established. If a foreign withholding tax is deducted, such amount is recorded separately and shown as income tax expense. For quoted equity securities, the date of recognition usually equals to the ex-dividend date.

Notes to the condensed consolidated interim balance sheet

6 Venture capital investments and notes receivable

6.1 Movements of cost and changes in fair value, prior year

	Cost 01.10.2014 USD	Additions USD	Disposals USD	Cost 31.03.2015 USD	Fair value 31.03.2015 USD
Biotechnology					
Osiris Therapeutics	24,173,023	0	0	24,173,023	72,136,032
Myriad Genetics	5,214,880	0	0	5,214,880	6,386,160
Prolexys Pharmaceuticals	15,000,000	0	0	15,000,000	500,000
Etex	2,664,248	0	(2,664,248)	0	0
Technology					
Reverb Networks	1,000,000	500,000	0	1,500,000	1,500,000
mPortal	10,370,000	0	0	10,370,000	8,156,880
Total	58,422,151	500,000	(2,664,248)	56,257,903	88,679,072

	Cumulative fair value adjustments 01.10.2014 USD	Gains USD	Losses USD	Increase due to disposals ¹ USD	Cumulative fair value adjustments 31.03.2015 USD	Dividend income USD
Biotechnology						
Osiris Therapeutics	27,487,536	20,475,473 ²	0	0	47,963,009	0
Myriad Genetics	1,743,148	0	(571,868) ³	0	1,171,280	0
Prolexys Pharmaceuticals	(14,500,000)	0	0	0	(14,500,000)	0
Etex	(1,321,460)	92,859 ⁴	0	1,228,601	0	0
Technology						
Reverb Networks	0	0	0	0	0	0
mPortal	2,542,500	0	(4,755,620) ⁵	0	(2,213,120)	0
Total investments	15,951,724	20,568,332	(5,327,488)	1,228,601	32,421,169	0

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).

⁴ The investment in Etex was sold at a price of USD 1,435,647, whereof the amount of USD 1,085,647 was received in cash. The remaining amount of USD 350,000 is expected to be received in a later period.

⁵ Based on valuation information from M&A process.

6 Venture capital investments and notes receivable (continued)

6.2 Movements of cost and changes in fair value, current year

	Cost 01.10.2015 USD	Additions USD	Disposals USD	Cost 31.03.2016 USD	Fair value 31.03.2016 USD	
Biotechnology						
Osiris Therapeutics	24,173,023	0	0	24,173,023	23,429,849	
Myriad Genetics	5,868,501	0	0	5,868,501	7,486,000	
Prolexys Pharmaceuticals	15,000,000	0	0	15,000,000	460,000	
Technology						
Reverb Networks	0	0	0	0	0	
Total	45,041,524	0	0	45,041,524	31,375,849	
	Cumulative fair value adjustments 01.10.2015 USD	Gains USD	Losses USD	Released due to disposals ¹ USD	Cumulative fair value adjustments 31.03.2016 USD	Dividend income USD
Biotechnology						
Osiris Therapeutics	51,614,946	0	(52,358,120) ²	0	(743,174)	820,660
Myriad Genetics	1,627,499	0	(10,000) ³	0	1,617,499	0
Prolexys Pharmaceuticals	(14,500,000)	0	(40,000) ⁴	0	(14,540,000)	0
Technology						
Reverb Networks	0	160,000 ⁵	0	(160,000)	0	0
Total investments	38,742,445	160,000	(52,408,120)	(160,000)	(13,665,675)	820,660

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). The quoted price per share decreased from USD 18.47 (30.09.2015) to USD 5.71 (31.03.2016).

³ Based on quoted price of the Myriad Genetics shares on NASDAQ (MYGN).

⁴ Based on DCF calculation.

⁵ The investment in Reverb Networks was fully written off in previous period due to insolvency of the company and has paid an unexpected liquidation dividend in current period of USD 160,000.

7 Financial instruments and fair value

7.1 Fair value information

Valuation of financial instruments

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.

Fair value of venture capital investments:

Venture capital investments and notes receivable for which fair values were:	31.03.2016		30.09.2015	
	USD	%	USD	%
- determined directly by reference to published price quotations	30,915,849	99%	83,283,969	99%
- determined using valuation techniques ¹	460,000	1%	500,000	1%
Total carrying amount	31,375,849	100%	83,783,969	100%

The total amount of the change in fair value estimated using a valuation technique that was recognized in the statement of comprehensive income in the current period amounted to a net profit of USD 120,000 (prior interim period: net loss of USD 4,662,761).

¹ This value was determined using valuation techniques that are not supported by observable market prices or rates.

7 Financial instruments and fair value (continued)

7.1 Fair value information (continued)

The following is an overview of assumptions and valuation techniques applied to investments without published price quotations on a company by company basis:

Prolexys Pharmaceuticals: Prolexys is developing pharmaceutical cancer products against multiple melanoma. The product has very high risk / return characteristics. The company finished its phase I/II trial with mixed results. The company is now in the process of analyzing the value of the product based on the results of the trial and to find a potential partner for the further development of the product if applicable. Based on the uncertainty of the value of the product, the risk of a loss of the investment is high and real. The outcome of this process is crucial for the survival of the company. So far there was no positive outcome in the search of a partner. Therefore, we further increased the discount factor in our valuation calculation which reduced the valuation of the investment in the reporting period. The WACC and the DCF calculation changed accordingly. The high WACC is reflecting the over average risk of the investment.

Additional information regarding investments with published price quotations:

Osiris Therapeutics: Osiris Therapeutics identified accounting errors during the course of its ongoing review of its accounting for revenue recognition under contracts with distributors that was previously disclosed in November 2015 in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and its Current Report on Form 8-K filed with the SEC on November 20, 2015. In those reports, the Company previously disclosed its intention to restate its previously issued interim financial statements for the first quarter and second quarter of 2015 and to make immaterial modifications to its audited financial statements for the year ended December 31, 2014.

Based on its review to date, the Company preliminarily anticipates that the restatements will focus on the timing of revenue recognition under contracts with distributors in accordance with US GAAP and is expected to result in restating certain revenues under a cash, rather than accrual, basis of accounting, which means that revenues are recognized based upon actual cash receipt. The anticipated adjustments are expected to reduce distributor revenues previously recognized in 2014 and 2015 while increasing distributor revenues previously recognized in 2015 or in future periods during 2016. The revenue adjustments will necessitate corresponding changes to other items in the financial statements including cost of goods sold, commission expense, accounts receivable and inventory. The Company is working diligently to quantify the expected revisions and have them reviewed by its former independent public accounting firm.

7 Financial instruments and fair value (continued)

7.2 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.

31.03.2016	Carrying amount USD	Fair value			Total USD
		Level 1 USD	Level 2 USD	Level 3 USD	
Cash and cash equivalents	3,920,353				
Total loans and receivables	3,920,353				
Venture capital equity investments and notes receivable	31,375,849	30,915,849	0	460,000	31,375,849
Total designated at fair value through profit or loss	31,375,849				
Accrued advisory fees	43,507				
Other accrued expenses	113,626 ¹				
Loans payable to related parties	6,913,778	0	0	6,913,186 ²	6,913,186
Bank loan payable	1,500,752				
Convertible bonds	15,657,552 ³	0	0	15,754,513 ²	15,754,513
Total financial liabilities at amortized cost	24,229,215				
30.09.2015	Carrying amount USD	Fair value			Total USD
		Level 1 USD	Level 2 USD	Level 3 USD	
Cash and cash equivalents	4,287,464				
Total loans and receivables	4,287,464				
Venture capital equity investments and notes receivable	83,783,969	83,283,969	0	500,000	83,783,969
Total designated at fair value through profit or loss	83,783,969				
Accrued advisory fees	175,238				
Other accrued expenses	216,531 ¹				
Loans payable to related parties	6,847,961	0	0	6,847,961 ²	6,847,961
Bank loan payable	1,500,740				
Convertible bonds	15,767,875 ⁴	0	0	15,889,886 ²	15,889,886
Total financial liabilities at amortized cost	24,508,345				

Basis for determination of the fair values:

The carrying amounts of cash equivalents, bank loans payable, accounts receivable, accounts payable and accrued expenses due to the short maturity approximate fair value.

For the determination of the fair value of the venture capital investments refer to note 7.1.

The fair value of the loans payable to related party and convertible bonds is determined by discounting the future contractual cash flows. The applied discount factor of 4.0% is the USD government yield curve plus a credit spread for a B+ rated investment for both periods.

¹ The difference to the amount stated in the balance sheet relates to accruals for taxes.

² As the Group revisited its process for the allocation of financial instruments in the fair value hierarchy, the fair value hierarchy for the "loans payable to related parties" and the "convertible bonds" has been restated compared to the latest semi-annual report per March 31, 2015.

³ Accrued interests amounting to USD 116,431 included.

⁴ Accrued interests amounting to USD 424,510 included.

7 Financial instruments and fair value (continued)

7.3 Equity investment Level 3

The carrying amounts of the Group's other financial assets and liabilities at the balance sheet date approximated their fair values.

The following table shows a reconciliation from the beginning balances to the ending balances for fair value measurements in Level 3 of the fair value hierarchy:

Unlisted equity investment Level 3

	Six months ended March 31, 2016 USD	Twelve months ended September 30, 2015 USD
Total as of October 1	500,000	15,755,288
Total gains and losses recognised in profit or loss included in		
- Gains on venture capital investments	160,000	92,859
- Losses on venture capital investments	(40,000)	(7,373,110)
Purchases	0	1,350,000
Redemption	0	0
Disposals	(160,000)	(9,325,037)
Total as of the end of the period	460,000	500,000

During the six months ended March 31, 2016, there occurred no transfers between the Levels. Gains on venture capital investments (USD 160,000) and disposals (USD 160,000) relates to received liquidation dividend of fully written off investment in Reverb Networks. USD 40,000 of the losses on venture capital investments disclosed above refer to investments still held at the balance sheet date.

During the twelve months ended September 30, 2015, there occurred no transfers between the Levels. USD 92,859 of the gains and USD 7,373,110 of the losses on venture capital investments disclosed above refer to investments sold or written off.

Other notes

8 Related parties

8.1 Investment Advisor

Since January 1, 2013, Madison Investment Advisor, Inc., Panama is the investment advisor of Venturetec, Inc. The investment advisor supports and advises the Board on specific duties with regards to the selection, purchase, sale, structure and disposal of the Group's investments. For the previous period, the fees have been 0.6% of the net asset value per annum plus up to 0.5% of the net asset value per annum for costs. Starting October 1, 2014, the Board of Directors and the Investment Advisor agreed to change the fee to an all inclusive 1.00% of the net asset value per annum without any additional costs to be reimbursed by the Company.

Mr. 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 a member of the Board of Directors of certain investees. As Chairman of the Board of Directors of the Investment Advisor of New Venturetec and other investment companies, he may be able to exercise significant influence or control over the Company's investees.

8.2 Board of Directors

USD 25,203 were accrued as fees to the Board Directors for the period under review and USD 50,405 were paid out related to accrued fees for prior periods (2015: USD 26,082 accrued and USD 52,165 paid out). These fees are included in the general and administrative expenses.

8.3 Loans and convertible bonds payable to related parties

Loans payable to related parties a.o. 31.03.2016	Principal USD	Accrued Interests USD	Total USD
4% secured promissory note ¹⁾	5,287,046	52,870	5,339,916
4% secured promissory note ²⁾	1,558,280	15,582	1,573,862
Total	6,845,326	68,452	6,913,778

Loans payable to related parties a.o. 30.09.2015	Principal USD	Accrued Interests USD	Total USD
4% secured promissory note ¹⁾	5,228,922	52,289	5,281,211
4% secured promissory note ²⁾	1,541,149	25,601	1,566,750
Total	6,770,071	77,890	6,847,961

All loans payable to related parties are entered into with Mr. Peter Friedli.

- 1) On May 2, 2014, outstanding promissory notes of CHF 2,816,269 and CHF 2,273,041 due to Mr. Friedli were combined and replaced by a 4% secured promissory note due to Mr. Friedli in the total amount of CHF 5,089,310, due on December 31, 2014. The term of the note will be automatically extended by six month on each consecutive maturity date and the current due date is June 30, 2016. The note can be terminated on each maturity date by either party upon a 3 month written notice. The note was not terminated as per June 30, 2016.
- 2) On April 23, 2015, New Venturetec Ltd. issued a 4% secured promissory note due to Mr. Friedli in the amount of CHF 1,500,000, due on December 31, 2015. The term of the note will be automatically extended by six month on each consecutive maturity date and the current due date is June 30, 2016. The note can be terminated on each maturity date by either party upon a 3 month written notice. The note was not terminated as per June 30, 2016.

The notes are secured by all tangible and intangible assets of New Venturetec Ltd.

8 Related parties (continued)**8.3 Loans and convertible bonds payable to related parties (continued)**

Convertible bonds payable to related parties a.o. 31.03.2016	Principal USD	Accrued Interests USD	Total USD
4% convertible bonds payable to Mr. Friedli	12,387,476	92,805	12,480,281
4% convertible bonds payable to Mr. von Sprecher	51,614	387	52,001

Convertible bonds payable to related parties a.o. 30.09.2015	Principal USD	Accrued Interests USD	Total USD
4% convertible bonds payable to Mr. Friedli	12,229,849	338,367	12,568,216
4% convertible bonds payable to Mr. von Sprecher	50,958	1,410	52,368

8.4 Interests on loans and convertible bonds payable to related parties

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

Interests on loans and convertible bonds payable to related parties	Six months ended 31.03.2016 USD	Six months ended 31.03.2015 USD
4% secured promissory notes to Mr. Friedli	132,854	106,193
4% convertible bonds to Mr. Friedli	262,988	272,129
4% convertible bonds to Mr. von Sprecher	1,096	1,134
Total interests on loans from related parties	396,938	379,456

8.5 Related party transactions

- Advisory fees in the amount of USD 151,875 were recognized for the investment advisor for the six months period ended March 31, 2016 (previous six months period: USD 301'301).
- Interest on loans and bonds to related parties in the amount of USD 396,938 (previous six months period: USD 379,456) were recognized in the reporting period.
- Board of Directors fees accrued from the fiscal year 2014/15 in the amount of USD 50,405 (previous period: USD 52,165) were paid out.

9 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 31.03.2016 USD	Six months ended 31.03.2015 USD (restated)
(Loss) / Profit attributable to ordinary shareholders (basic)	(52,273,431)	14,552,789
Interest expenses on convertible bonds, net of tax	329,940	341,408
Profit attributable to ordinary shareholders (diluted)	(51,943,491)	14,894,197
Weighted-average number of ordinary shares		
- outstanding a.o. balance sheet date (basic)	5,000,000	5,000,000
- that would be issued at conversion	1,584,737	1,584,737
Total weighted-average number of ordinary shares (diluted)	6,584,737	6,584,737
Earnings per share (basic)	(10.45)	2.91
Earnings per share (diluted)	(7.89)	2.26

The Group determined that its calculation of diluted earnings per share presented in the interim consolidated financial statements as at March 31, 2015, had been erroneous. As a consequence, in the half year diluted earnings per share have been disclosed incorrectly in the consolidated statement of comprehensive income and in note 16 "Earnings per share". The error is corrected in the condensed consolidated interim financial statements as at March 31, 2016, by restating the line item of the consolidated statement of comprehensive income and the note 9. The diluted earnings per share as at March 31, 2015, amounted to USD 2.26 and not as previously reported USD 2.91.

10 Subsequent events

The interim consolidated financial statements were authorized for issue by the Board of Directors on May 9, 2016.

The balance sheet of the New Venturetec Ltd. showed that one-half of the share capital and the legal reserves are no longer covered as per Art. 725 para. 1 CO. The Board of Directors analyzed and discussed the situation and deemed it as in the best interest of the Company and its shareholders to take the following action to address the capital loss:

On May 9, 2016, Peter Friedli and the Company signed a subordination agreement to address the capital loss of the company in accordance with Art 725 para. 1 CO. The total subordinated claim under this agreement of CHF 18'655'894 per March 31, 2016 is deferred and cannot be repaid as long as a balance sheet or interim balance sheet audited in accordance with Swiss Auditing Standards shows that the Company is not in a situation of a capital loss in accordance with Art 725 para. 1 CO anymore.

The Board of Directors is not aware of any further events between March 31, 2016 and May 9, 2016, which would require adjustment to the carrying amounts of the Group's assets and liabilities as of March 31, 2016 or would require disclosure under this heading.

Annex I

Risk factors of Osiris Therapeutics as per the Osiris Therapeutics annual report 2014

Risk Factors.

Risks Related To Our Business

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

Until fiscal 2009, we incurred losses in each year since our inception, and may incur additional losses over the next several years. As of December 31, 2014, we had an accumulated deficit of \$203.5 million. These losses resulted principally from costs incurred in our research and development programs and from our general and administrative expenses. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

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

- Complete our confirmatory Phase III quality random clinical trial with Grafix for complex diabetic foot wounds with exposed tendon or bone;
- continue other studies and initiate and pursue additional studies and possible clinical trials for our Biosurgery products, including Grafix for venous leg ulcers, which we have begun, and possibly other potential indications;
- manage regulatory issues and requirements related to the marketing and distribution of our products and product candidates, including issues related to FDA approval and third party payor reimbursement;
- maintain, expand and protect our intellectual property; and
- continue to add sales, operational, financial, accounting, facilities engineering and information systems personnel, consistent with expanding our operations.

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

The current credit and financial market conditions may exacerbate certain risk affecting our business.

We rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors, contract clinical trial providers, contract manufacturers and third-party suppliers. Because of the tightened global credit and continuing volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

We depend on key personnel.

Our future success depends to a significant extent on the skills, experience and efforts of our scientific, management, and sales personnel. These include Lode Debrabandere Ph.D., Alla Danilkovitch, Ph.D., Philip R. Jacoby, Jr., and Frank Czworka. We also rely upon the guidance and experience of Peter Friedli, the Chairman of our Board of Directors. The loss of any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. We are party to an employment agreement with Dr. Debrabandere. The existence of an employment agreement does not, however, guarantee retention of any officer or employee, and we may not be able to retain any of these individuals, whether or not we have an employment agreement with them. Except for Dr. Debrabandere, none of our employees is employed for a specified term. Competition for personnel is intense. We may be unable to retain our current personnel or attract or integrate other qualified management and scientific personnel in the future.

The potential of our Biosurgery products and products under development to treat conditions may not be realized.

We are continually evaluating the potential of our Biosurgery products and products under development. Our products are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate efficacy or other characteristics that may prevent or limit their commercial use, or if required, marketing approval. If the treatment potential of our products is not realized, the value of our technology, our development programs and our products could be significantly reduced. Because our Biosurgery products are comprised of human tissue, any negative developments regarding the therapeutic potential or side effects of human tissue products could have a material adverse effect on our business, financial condition and results of operations.

Our product development programs are based on novel technologies and 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 products and product candidates creates significant challenges in regards to product development and optimization, processing and manufacturing, government regulation, third-party reimbursement and market acceptance. For example, questions persist with regard to the necessity of FDA approval for some cell-based products, and therefore, the pathway to commercialization of our Biosurgery products may be more complex and lengthy. Additionally, 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 may be subject to increased uncertainty, as compared to the pathway for conventional products.

Our Biosurgery products represent new classes of therapy that the marketplace may not understand or accept.

The market may not understand or accept our products. We are developing products that represent novel treatments or therapies and which will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The novel nature of our Biosurgery products creates significant challenges in regards to product development and optimization, manufacturing, government regulation, and third-party reimbursement. As a result, the development pathway for our Biosurgery products may be subject to increased scrutiny, as compared to the pathway for more conventional products.

The degree of market acceptance of any of our developed or potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;

- our ability to convince health care providers that the use of our products in a particular procedure is more beneficial than the standard of care or other available methods;
- our ability to explain clearly and educate others on the use of human placental tissue, to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue;
- ethical controversies that may arise regarding the use of human tissue of any kind, including tissues derived from deceased donor, and distribution for profit of our deceased donor products;
- adverse reactions involving our biosurgery products or the products or product candidates of others that are human tissue based;
- our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and
- the cost of our products and the reimbursement policies of government and third-party payors.

If the health care community does not accept our potential products for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations.

The successful commercialization and distribution of our Biosurgery products will depend on obtaining reimbursement from third-party payors.

We distribute our Biosurgery products in the United States. We may expand our distribution to other countries in the future. In the United States and elsewhere, the market for any pharmaceutical or therapeutic product is affected by the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. Biosurgery products like Grafix, Cartiform and BIO⁴ 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, may make it more difficult for us to obtain adequate reimbursement from third-party payors, particularly if we cannot demonstrate a favorable cost-benefit relationship. Third-party payors may also deny coverage or offer inadequate levels of reimbursement for our products if they determine that the product has not received appropriate clearances from the FDA or other government regulators or is experimental, unnecessary or inappropriate.

In the countries of Europe and in some other countries, the pricing of prescription and therapeutic products and services, and reimbursement, are subject to increased governmental control. In addition, many other countries require pre-marketing approval for human tissue based products, or otherwise more extensively regulate human tissue based products than does the United States.

Regardless of whether we are required to conduct a successful clinical trial in order to market a product in the United States or a foreign country, we may nevertheless be required to conduct one or more clinical trials, and to publish one or more peer reviewed journal articles supporting the product, before we are able to obtain third party reimbursement. We may also be required to conduct additional clinical trials that compare the cost effectiveness of our products to other available therapies before third party payors will provide reimbursement. Conducting clinical trials is expensive and will result in delays in wide scale commercialization and reimbursement. Publishing of peer reviewed journal articles may also be costly and result in delays. In addition, even if our products otherwise meet the requirements for reimbursement, pricing negotiations with third party payors may take months and result in significant delay in obtaining approval for reimbursement.

Reimbursement policies also sometimes differ depending upon the setting in which the product is to be used. The use of our Biosurgery products in a hospital setting as part of a surgical or other more extensive procedure may have a reimbursement pathway that differs from a use in an outpatient setting for a more narrowly defined procedure. Thus, for example, the reimbursement pathway for Grafix—which we expect to be used more often in an outpatient setting—may differ from that for BIO⁴—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 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 us or our business.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and of foreign governments. Although we do not believe that any recently enacted or presently proposed U.S. legislation should impact our business specifically and negatively as compared to other health care product businesses generally, we might nevertheless be subject to future regulations or other cost-control initiatives that materially restrict the price we receive for our products. In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

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

Our Biosurgery products consist of human tissue. This tissue is obtained by us from not-for-profit donor procurement agencies. Grafix is processed from human placental tissue. BIO⁴ is processed from deceased donor bone. Cartiform is processed from deceased donor cartilage. While we are not aware of significant supply issues, and placental tissue and deceased donor bone and cartilage is generally available to us, the supplier agencies may not be able to provide us with sufficient amounts of tissue to meet the demand. In addition, the use of human tissue as a 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 Biosurgery products, we may not be able to secure quantities of human tissue sufficient to meet the demand.

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

The utilization of human tissue creates the potential for transmission of communicable disease, including but not limited to human immunodeficiency virus (HIV) viral hepatitis, syphilis, Creutzfeldt-Jakob disease, or the human form of "mad cow" disease, and other viral, fungal or bacterial pathogens. Although we are required to comply with federal and state regulations intended to prevent communicable disease transmission, and our suppliers of adult human bone, cartilage and placental tissue are also required to comply with such regulations in connection with their collection, storage and supply to us:

- we or our suppliers may fail to comply with such regulations;
- 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.

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

We may encounter difficulties in the production of our Biosurgery products due to our limited manufacturing capabilities. This difficulty could reduce redistribution efforts of our products, increase our distribution costs or cause production delays, any of which could damage our reputation and effect our operations. Even if we have access to quantities of human tissue sufficient to allow us otherwise to expand our manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all.

We use or may use third-party collaborators to help us develop and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful.

We have arrangements in place with third-party collaborators as a means to help us with research and development efforts or marketing and distribution. We are subject to a number of risks associated with our dependence upon our collaborative relationships, including:

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

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

Our most significant collaborative arrangement is with a subsidiary of Stryker Corporation, and our success

may depend upon performance on the part of Stryker and the success of this collaboration. We are also dependent upon our exclusive partnership with Arthrex, Inc. for the commercial distribution of Cartiform, and may enter into and become dependent upon additional collaborations in the future.

We are party to an Exclusive Service Agreement with Howmedica Osteonics Corp., also referred to as Stryker Orthopaedics, a subsidiary of Stryker Corporation ("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 promoter of allograft services for BIO⁴ for use in surgical applications, including spine, trauma, extremity, cranial, and foot and ankle surgery. This collaboration is subject to all of the risks and uncertainties applicable to collaborative arrangements generally, including those described above. In addition, this collaboration is subject to a number of risks and uncertainties specific to the transaction and the parties.

The agreement with Stryker provides for an initial four year exclusive term, commencing on the date of Stryker's initial commercial sale. The term may be extended by Stryker for an additional exclusive period of four years or an additional non-exclusive period of two years. If Stryker extends the term on an exclusive basis, it has the option to further extend the term on an exclusive basis for two years. Osiris is entitled to receive an initial exclusivity fee of \$5,000,000 and additional fees upon any exercise by Stryker of its right to extend the initial term, whether on an exclusive or non-exclusive basis. These additional fees are reduced on a sliding scale if Stryker meets certain revenue thresholds during the initial term, or if revenue goals are not met as a result of Osiris not fulfilling its supply obligations. Stryker is entitled to a certain percentage of sales of allograft services for BIO⁴ and has limited early termination rights. The success of this collaboration for us will in part be dependent upon Stryker, including its success in marketing and promoting BIO⁴.

Stryker has significantly greater resources than we do, and this collaboration is not as core to its business as it is to ours. We are dependent upon Stryker's continued performance under this collaboration, 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 are also dependent upon our exclusive commercial and development partnership with Arthrex, Inc., to which we have granted exclusive commercial distribution rights for Cartiform, 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 collaborations in the future. We are dependent upon our current collaborators, and will be dependent upon any future collaborators, in performing their responsibilities in connection with the relevant collaboration. If we fail to maintain our existing or any future collaborative relationships for any reason, we would need to undertake on our own and at our own expense, or find other collaborators, to perform the activities we currently anticipate will be performed by our collaborators. 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 find other collaborators on acceptable terms, or at all. This may limit the programs we are able to 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 and as to inventory accounting.

We have historically distributed our Biosurgery products either ourselves or through third party distributors who sometimes take possession of our inventory on a consignment basis, or through a combination of both methods. In some situations, we store consigned inventory on site in freezers at hospital or clinic facilities. We commercialize Grafix through the efforts of our own focused direct distribution and marketing staff, as well as through a network of specialty distributors for certain target markets. Like Ovation and OvationOS, Bio⁴ will sometimes be commercialized through a consignment arrangement, and our agreement with Stryker includes consignment terms, as does our agreement with Arthrex for Cartiform. Because our consigned inventory must be stored at -80 C, it is at risk of thawing, resulting in the loss of that inventory. That risk of loss of is borne by us, although we believe that we maintain adequate insurance to cover the risk. Inventory management is complicated by a consignment arrangement, as is revenue recognition and inventory and receivables accounting. Thus, for example, 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. This may not occur in a timely manner, meaning that our financial statements may not always reflect our actual inventory and receivables

balances as of the end of a fiscal period. We monitor and verify the condition and status of all consigned inventory on at least a quarterly basis, at additional expense to us. In addition, FDA, AATB and other accrediting agency 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, as is the case with all of our inventory, 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 withdraw of necessary approvals or other qualifications allowing for the distribution and sale of that inventory, the value of that inventory may have to be 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 are currently dependent upon third-parties for services and raw materials needed for the processing of our Biosurgery products, and for distribution.

In order to produce our Biosurgery products we require biological media, reagents and other highly specialized materials. This is in addition to the human tissue donations used to manufacture our biosurgery products. These items must be manufactured and supplied to us in sufficient quantities and in compliance with cGMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to cGMP standards.

We expect to continue to rely on third parties to sell or redistribute our biosurgery products. Proper shipping and distribution requires compliance with specific storage and shipment procedures. Failure to comply with these procedures or the occurrence of inadvertent damage to the shipping container will necessitate return and replacement, potentially resulting in additional cost and causing us to fail to meet supply requirements. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised, and our business would be harmed.

Our dependence on third parties may increase the risk that we will not have adequate quantities of our biosurgery products.

Our Biosurgery product supply chain and processing infrastructure depends on the performance of a number of complex contracts between us on the one hand and our suppliers and redistributors on the other. If any of our suppliers, distributors or other business partners 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 such components ourselves, including:

- reliance on the third party 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.

Our suppliers, distributors and other third parties with which we contract are subject to many or all of the risks and uncertainties that we are subject to. 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 cGMP 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 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 of our products and could have a material adverse effect on our business, financial condition and results of operations.

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

If our processing 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 approximately 61,203 square feet of space in Columbia, Maryland that houses essentially all of our corporate operations. Currently, we maintain insurance coverage totaling \$22.8 million against damage to our property and equipment, an additional \$5.0 million to cover business interruption and extra expenses, and \$7.3 million to cover 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.

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 Biosurgery products depends in part on general public acceptance of the use of human tissue for the treatment of human diseases and other conditions. While not as controversial as the use of embryonic stem cells and fetal tissue, the use of placental tissue and adult tissue has been the subject of substantial debate regarding related ethical, legal and social issues. We do not use embryonic stem cells or fetal tissue, but the public may not be able to, or may fail to, differentiate our use of placental or adult 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.

Many of our competitors have greater resources or capabilities than we have, or may succeed in developing better products or in developing 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 and our other Biosurgery products and products under development. In many cases, the competing product or candidate is based on traditional pharmaceutical, medical device or other therapies and technologies. Competitors competing with our Biosurgery products include, but are not limited to: Organogenesis, the manufacturer of Apligraf and Dermagraft and MiMedx, the manufacturer of EpiFix which competes with Grafix. BIO 4 competes with bone tissue products such as Osteocel® and Trinity®, while Cartiform competes with cartilage allografts. In addition to those listed above, we have other existing and potential competitors developing a variety of treatments and therapies for the same conditions for which we market our products.

We also face competition in the cellular regenerative field from academic institutions and governmental agencies. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in research and development and more established marketing and distribution capabilities.

We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render products now or in the future under development by us, or any products manufactured or marketed by us, non-competitive or otherwise obsolete.

The use of our Biosurgery 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. None of our products have been widely used over an extended period of time, and therefore our safety data is limited. 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;
- withdrawal of clinical trial participants; or
- adverse regulatory action.

Any of these results 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 regulatory approval and reimbursement processes, we will incur additional operating expenses in connection with the expansion of our Biosurgery business.

We expect to continue to incur significant operating expenses in connection with our planned expansion of our biosurgery 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 and other Biosurgery 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 additional manufacturing, quality control, and quality assurance, and management personnel as necessary to expand our processing operations;
- expand our processing capacity for our Biosurgery products, which will require that we maintain a portion of our space as an FDA compliant and validated product manufacturing facility; and
- expand and protect our intellectual property portfolio for our Biosurgery products.

Our redistribution fees from our Biosurgery products have been limited to date. 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.

Risks Related to Regulatory Approval and Other Government Regulations

Should the FDA determine that any of our products do not meet regulatory requirements that permit qualifying human cells, tissues and cellular and tissue-based products to be processed, stored, labeled and distributed without pre-marketing approval, we may be required to stop processing and distributing such products, or to narrow the indications for which those products are marketed.

The FDA has developed a tiered, risk-based regulatory framework, which includes criteria for facility management, quality assurance, donor selection, and processing of human cells, tissues, and cellular and tissue based products. We believe that commercial sale of Grafix as a wound allograft for the treatment of acute and chronic wounds, including diabetic foot ulcers, does not require pre-market approval by the FDA because we believe that this product meets the regulatory definition of human cells, tissue, and cellular and tissue-based products, or so-called Part 361 HCT/Ps (meaning that they comply with section 361 of the Public Health Service Act (PHSA) and 21 CFR 1271). We received an "untitled letter" dated September 26, 2013 from the FDA stating,

among other things, that both Grafix and Ovation do not meet these regulatory requirements because they are dependent upon the metabolic activity of living cells for their primary function and are not intended for autologous use or allergenic use in a first or second degree relative; and that Ovation does not meet the minimal manipulation criterion. After discussions with, and providing additional information to, the FDA, we reached an agreement with the FDA confirming the regulatory status of Grafix and allowing the product to remain on the market as an HCT/P and without FDA pre-marketing approval, as a wound allograft for the treatment of acute and chronic wounds. We further committed to the FDA that, before marketing Grafix for certain expanded indications, we would submit a Biologics License Application (BLA) to the FDA and seek pre-marketing approval for any such additional indication. We also agreed to continue to transition our Ovation product line over to OvationOS (now branded as BIO⁴) by no later than the second half of 2014, which we did. In August 2014, we stopped distributing promotional materials for Ovation and ceased manufacturing the product. In October 2014, we stopped shipping Ovation from our Columbia, MD facilities. At December 31, 2014, we owned some units of Ovation located in the field for use in procedures by the end users. We believe that commercial distribution of BIO⁴, a viable bone matrix for bone growth, and Cartiform, a viable chondral allograft, does not require pre-market approval by the FDA because we believe that these products meet the regulatory definition of HCT/Ps.

We engage in ongoing discussion and communication with FDA representatives regarding the applicable regulatory requirements and pathways for our products and product candidates. The analysis and determination of compliance of a product with these regulatory requirements and pathways is complex and dependent upon numerous factors, and is readily subject to varying interpretations and conclusions. The FDA may not agree with our views on these matters. Should the FDA decide that Grafix, BIO⁴ or any of our other Biosurgery products do not meet the regulatory definition of HCT/Ps, we will not be able to produce and redistribute 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 ability to expand the marketing claims for Grafix and BIO⁴ is limited by Federal regulations, and will likely require the submission to the FDA of a biologics license application, or BLA, and the receipt of pre-marketing approval from the FDA, for the particular indication.

We cannot process, market or distribute our Biosurgery products without compliance with the United States Food Drug and Cosmetics Act, and comparable laws in foreign countries. Part 361 HCT/Ps may be processed, stored and distributed in the United States without FDA approval, provided that the product complies with the requirements of Part 361 of the PHS Act and 21 CFR 1271. Absent such compliance, a BLA is required as a condition to marketing and sale of the product. In order to obtain a BLA we would be required to conduct extensive preclinical studies and clinical trials to demonstrate that the product is safe and effective and obtain required regulatory approvals. This process is costly and the product may fail to perform as we expect. Moreover, a product may ultimately fail to show the desired safety and efficacy traits despite having progressed successfully through preclinical or initial clinical testing. We would need to devote significant additional research and development, financial resources and personnel to obtain the necessary regulatory approvals, if required.

We have initiated efforts to obtain a BLA for Grafix. For the current label indications, for Grafix and BIO⁴, we rely upon the exception to the BLA limits requirement afforded Part 361 HCT/Ps. However, compliance with these requirements our activities in respect of these products. For example, we will not be able to enhance tissue based products in a manner which would result in the product being more than "minimally manipulated" within the meaning of 21 CFR 1271. These and other limitations applicable to HCT/Ps limit the indications for which these products may be marketed. Moreover, the FDA continues to review and inspect marketed products, manufacturers and manufacturing facilities, and even if a BLA is not required initially, the FDA or its foreign equivalents may create additional regulatory burdens in the future or may reevaluate or modify current regulatory frameworks in a manner adverse to us. Later discovery of previously unknown problems with a product, manufacturer or facility—including those of or associated with a competitor or competing product—may result in the imposition of additional restrictions on us or our products, including a withdrawal of the product from the market. This would have a material adverse effect on our business, financial condition and results of operations.

If we are not able to conduct clinical trials properly and on schedule, or if any such clinical trials prove to be unsuccessful, we would be unable to secure sought after, or any required, regulatory approvals.

We are currently pursuing and in the future may pursue additional clinical trials for our Biosurgery products to enhance our ability to successfully market these products, or to obtain pre-marketing approval if required by the FDA for us to market certain products, or to market our products for expanded indications. Clinical trials are costly and time consuming. The completion of clinical trials may be delayed or terminated, or the costs may be increased, for many reasons, including, but not limited to, if:

- the FDA does not grant permission to proceed and places the trial on clinical hold;
- subjects do not enroll in our trials at the rate we expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or Institutional Review Boards (IRBs) of research institutions participating in our clinical trials find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or
- one or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial.

If we are unable to conduct clinical trials properly and on schedule, any potential marketing benefit may be lost, the reputation of the product could be damaged, and any required marketing approval may be delayed or denied by the FDA.

Tissue based products are generally subjected to greater regulatory scrutiny in many other countries as compared to the United States. These requirements may be costly and result in delay or otherwise preclude the distribution of our Biosurgery products in some foreign countries, any of which would adversely affect our ability to generate operating revenues.

Tissue based products are regulated differently in different countries. We believe that commercial distribution of Grafix as a wound allograft for the treatment of acute and chronic wounds, including diabetic foot ulcers, and the commercial distribution of BIO⁴, a viable bone matrix for bone growth, do not require pre-market approval by the FDA in the United States because we believe that these products meet the regulatory definition of human cells, tissue, and cellular and tissue-based products, and qualify as Part 361 HCT/Ps. Many foreign jurisdictions have a different and more difficult regulatory pathway for human tissue based products, which may prohibit the distribution of these products until the applicable regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and we may never seek such approvals, or if we do, we may never gain those approvals. Any sought after or required approvals in Europe will likely require that we conduct clinical trials, which are themselves are costly and time consuming, and subject to risk and uncertainty, and may prove to be unsuccessful. Any adverse events in our clinical trials for one of our products could negatively impact our other products.

If we seek regulatory approval in the United States or elsewhere for our Biosurgery products, whether to enhance our ability to successfully market these products, or if we are required to do so by the FDA or equivalent foreign regulatory agencies, we may not be successful.

Should we decide to seek regulatory approval in the United States or elsewhere for our Biosurgery products, or should we be required to obtain such approvals before we can market a product generally or for a specific indication, any of the following factors may cause marketing approval to be delayed, limited or denied:

- our products will require significant pre-clinical and clinical development before applications for marketing approval can be filed with the FDA;
- data obtained from preclinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and the FDA or its foreign counterpart may not agree with our interpretations;
- it may take many years to complete the testing of our products, and failure can occur at any stage of the process;
- negative or inconclusive results or adverse side effects during a clinical trial could cause us to delay or terminate development efforts for product;
- approval may be delayed if the FDA or its foreign counterpart requires us to expand the size and scope of the clinical trials; or
- negative results from clinical trials or failure to obtain pre-marketing approval of a HCP/T product not otherwise requiring such approval may result in a negative public perception of the product and loss of market share and revenue.

If we seek marketing approval—whether or not then necessary to market a particular product—and that approval marketing approval is delayed, limited or denied, our ability to market products, and our ability to generate product sales, would be adversely affected.

We and our business are subject to rules and regulations regarding organ donation and transplantation.

Compliance with the issued operating standards established by The American Association of Tissue Banks ("AATB") is a requirement in order to become a licensed tissue bank. In addition, some states have their own tissue banking regulations. We are licensed to have permits as a tissue bank in Maryland, California, New York and Florida.

In addition, procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act ("NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with the development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we can recover in our pricing for our products, thereby reducing our future revenue and profitability. 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 results of operations.

In Europe, regulations, if applicable, differ from one country to the next. Because of the absence of a harmonized regulatory framework and proposed regulation for advanced therapy medicinal products in Europe, as well as for other countries, the approval process for human derived cell or tissue based medical products could be extensive, lengthy, expensive, and unpredictable. Our Biosurgery products are subject to the country's regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. These regulations include requirements for registration, listing, labeling, adverse-event reporting, and inspection and enforcement. Some countries have their own tissue banking regulations.

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, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. In the United States, 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.

Risks Related to Intellectual Property

Given our patent position in regard to our Biosurgery 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.

A significant amount of our technology, including our teaching regarding the processing of our Biosurgery products, is unpatented and is maintained by us as trade secrets or confidential know-how. In an effort to protect this proprietary information, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. 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 processing methodology and know-how for Grafix is protected by trade secret or through confidentiality arrangements. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships.

Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or know-how.

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, we will be subject to increased competition and our potential revenues from redistribution of these Biosurgery products may be limited.

Moreover, if our Biosurgery products infringe or are alleged to infringe intellectual property rights of third parties, 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 forced to stop or delay research, development, manufacturing or redistribution of the product that is the subject of the suit.

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 would 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 financial condition and results of operations.

The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has been the subject of much litigation. Neither the U.S. Patent and Trademark Office nor the courts has a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology patents.

The claims of our existing U.S. patents and those that may issue in the future, or those licensed to us, may not confer on us significant commercial protection against competing products. Even if we hold patents or have patent rights through licenses or otherwise with respect to a particular product, third parties may challenge, narrow, invalidate, design around, or circumvent any patents now or hereafter owned, assigned or licensed to us. Patents with broader claims tend to be more vulnerable to challenge by other parties than patents with extremely narrow claims. Also, our pending patent applications may not issue, may issue with substantially narrower claims than currently pending claims, or we may not receive any additional patents. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property.

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 significant amount of our technology, including our teaching regarding the production processes for our Biosurgery products, is unpatented and is maintained by us as trade secrets. The lack of patent protection for our Biosurgery 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 are unable to protect the confidentiality of our proprietary information, trade secrets and know-how, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.

Significant aspects of our Biosurgery product technology, especially the teaching regarding the manufacturing processes for these products, are unpatented and maintained by us as trade secrets or proprietary know-how. In an effort to protect these trade secrets and know-how, we require our employees, consultants, collaborators and advisors to execute confidential disclosure agreements before the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

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 would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

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

Our research, development and commercialization activities, and the manufacture or distribution of our Biosurgery 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 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 biologic drug candidate 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.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office and opposition proceedings before the patent offices for other countries (e.g. the European Patent Office) or similar adversarial proceedings, regarding intellectual property rights with respect to our products and technology. 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. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes may arise as to the rights related to or resulting from the use of such intellectual property.

We may become involved in lawsuits to protect or enforce our patents or the patents of our collaborators 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, 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 our patents or the patents of our collaborators 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 U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators 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 collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

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 the course of 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.

The biotechnology industry, including our fields of interest, is highly competitive and subject to significant and rapid technological change. Accordingly, our success will depend, in part, on our ability to respond quickly to such change through the development and introduction of new products. Our ability to compete successfully against currently existing and future alternatives to our products, and against competitors who compete directly with us, will depend, in part, on our ability to: attract and retain skilled scientific and research personnel; develop technologically superior products; develop competitively priced products; obtain patent or required regulatory approvals for our products; and be early entrants to the market; manufacture, market and sell our products, independently or through collaborations. If a third party were to commercialize a competitive product, there is no assurance that we would have a basis for initiating patent infringement proceedings or that, if initiated, we would prevail in such proceedings.

Risk Factors Regarding the Sale of our ceMSC Business

We may not receive all of the payments available to us under the terms of the Purchase Agreement, and accordingly, we may have less cash available to us to fund our operations.

The terms of our Purchase Agreement with Mesoblast for the sale of our ceMSC business provide for payment to us of \$50 million in initial consideration, and up to an additional \$50 million upon the achievement by Mesoblast of certain clinical and regulatory milestones. Additionally, we will be entitled to earn single to low double digit cash royalties on future sales by Mesoblast of Prochymal and other products utilizing the acquired ceMSC technology.

We have received all of the \$50 million in initial consideration, consisting of \$35 million in cash and \$15 million in Mesoblast ordinary shares. Payment of the initial consideration made in Mesoblast ordinary shares (\$15 million) was subject to a one-year holding period that ended in December 2014. We continue to hold these shares and Mesoblast has agreed to purchase the shares for at least \$15 million in cash prior to the middle of 2015. In the event that Mesoblast does not purchase these shares from us as agreed, the value of these shares will remain subject to market and foreign currency exchange risk, and we may be forced to liquidate these shares through other means and on terms materially less favorable to us. Our ability to receive the second \$50 million is subject to satisfaction of a series of milestones, all of which are largely dependent upon the clinical and regulatory success of Mesoblast and other factors not in our control. These include many if not all of the risks and uncertainties that our ceMSC business was subject to prior to its sale to Mesoblast, including product development, efficacy and regulatory risks. We have received no such payments thus far, nor do we have any expectation of receiving any such payments in the foreseeable future. Our ability to earn royalty payments from Mesoblast is subject to these same risks and will require performance by Mesoblast that results in its meeting some or all of the milestones referred to above, and is thereafter also dependent upon the commercial success of Mesoblast's ceMSC business. Royalties, if any, are payable to us in cash. Any portion of the second \$50 million that becomes payable to us will be payable, at the discretion of Mesoblast, in Mesoblast ordinary shares, based on a then current valuation of such shares.

Any portion of the second \$50 million in consideration paid in Mesoblast ordinary shares will also be, is subject to a one year holding period, again with limited downside protection for a drop in the Mesoblast share price over the holding period. Therefore, any such payment, if made, will be subject to investment risk, and because the Mesoblast ordinary shares are traded on the Australian Stock Exchange (ASX) and the per share price is denominated in Australian Dollars, will also be subject to foreign currency exchange risk.

Accordingly, not only do we have no assurances that any of the second \$50.0 million in consideration will ever be paid to or received by us, but also we may be unable to liquidate on favorable terms any amounts paid to us in Mesoblast ordinary shares. As a result, we may have less cash available to fund our remaining operations and to support the continued development and pursuit of our Biosurgery business, and our financial condition or results of operations could be materially adversely affected.

The Purchase Agreement exposes us to contingent liabilities and other risks that could adversely affect our business or financial condition.

In the Purchase Agreement, we have made customary representations and warranties and the parties have agreed to indemnify each other for breaches of representations, warranties and covenants contained in the Purchase Agreement. Also pursuant to the Purchase Agreement, we have retained a royalty free license to all transferred intellectual property, insofar as necessary for us to continue in our other businesses, including our Biosurgery business, and we have agreed not to compete with Mesoblast in the ceMSC business for a period of eight years. The Purchase Agreement also subjects us to other risks typical in business transactions of this type, including payment and performance risks. Should disputes arise or should we incur liability for breach of any of these representations, warranties or obligations, or should any of these other risks materialize, our business, financial condition or results of operations could be materially adversely affected.

Our long term business prospects will depend on the success of our Biosurgery business.

As a result of the sale of our ceMSC business, including Prochymal, our Biosurgery business is our sole remaining business, and our overall business is less diverse. Our long term business prospects will, therefore, be dependent almost entirely on the success of our Biosurgery business. This business involves significant risks and challenges in regards to product development and optimization, manufacturing, government regulation, intellectual property, third-party reimbursement and market acceptance, among other risks previously disclosed by us.

Payment of a portion of the purchase price for our Therapeutics business through the delivery of Mesoblast ordinary shares as permitted under the Purchase Agreement subjects us to significant additional risks.

Mesoblast ordinary shares delivered to us as payment under our Purchase Agreement with Mesoblast for the sale of our ceMSC business are subject to a one year holding period. Although we are afforded downside price protection for a drop over the holding period in the market price of Mesoblast ordinary shares delivered as payment, this downside protection is limited. To the extent the market price of the shares decreases over the holding period, Mesoblast has agreed to pay us for the decrease. This payment is to be made at least one half in cash and, at the option of Mesoblast, up to one half in additional shares of Mesoblast stock. Any additional Mesoblast stock will also have to be held for one year, for which period there will be no further downside price protection, and therefore the equity price risk will persist in respect of any additional Mesoblast shares issued to us. The Mesoblast ordinary shares are traded on the Australian Securities Exchange (ASX) and the share value is denominated there in Australian Dollars. Hence, there also exists an associated foreign currency exchange rate risk. There is no corresponding mitigation of the foreign currency exchange rate risk, and any devaluation of the Australian Dollar will directly impact the value of the Mesoblast shares to us.

Of the \$50 million in initial consideration, \$15 million has been paid to us in Mesoblast ordinary shares. Although we were initially subject to investment risk and foreign currency exchange risk in respect of our ownership of these shares, Mesoblast has agreed to purchase the shares for no less than \$15 million during the first half of 2015.

Nevertheless, any portion of the second \$50 million in consideration that may become payable to us under the Purchase Agreement (if and only if certain milestones are met by Mesoblast), is also payable to us, at the discretion of Mesoblast, in Mesoblast ordinary shares, based on a then current valuation of such shares. In the event of any negative events with respect to or otherwise affecting Mesoblast or the value of its ordinary shares, the value of any such additional Mesoblast ordinary shares acquired by us would be negatively affected and we could lose, in whole or in part, the value to us of that portion of the consideration paid to us by Mesoblast. If we are unable to liquidate on favorable terms any amounts paid to us in Mesoblast ordinary shares, we will have less cash available to fund our remaining operations and to support the continued development and pursuit of our biosurgery business, and our financial condition or results of operations could be materially adversely affected.

Risks Related to Our Common Stock

Although we have recently remediated a material weakness in our internal control over financial reporting, if we are unable to maintain the effectiveness of our internal controls, then a material misstatement could result in our financial statements.

We previously identified a material weakness in our internal control over financial reporting and, as a result of such weakness, our management, with the participation of our principal executive officer and principal financial officer, concluded that our disclosure controls and procedures and internal control over financial reporting were not effective as of December 31, 2013. The material weakness related to the maintenance of effective controls over the application and monitoring of our accounting for income taxes. With respect to our controls over the application and monitoring of our accounting for income taxes, we did not have controls designed and in place to ensure effective oversight of the work performed, and the accuracy of, financial information or professional conclusions provided by, third-party tax advisors. We have since remediated the material weakness through implementation of enhanced controls related to review and oversight of complex transactions and infrequent events. Additionally, we engaged a new third party tax advisor to oversee and prepare the Company's tax provision and other related documents. As a result, our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2014 no longer reports this material weakness or any other material weakness over financial reporting, and the audit report of our independent registered public accounting firm no longer expresses an adverse opinion on the effectiveness of our internal control over financial reporting as of December 31, 2014. Nevertheless, we may experience other material weaknesses in our internal control over financial reporting in the future, which could lead to or result in a material misstatement in our financial statements.

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:

- results of clinical trials or those of our competitors;
- regulatory developments in the United States and foreign countries, both generally or specific to us and our products;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- 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 and 5% stockholders;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our relationships with our collaborators; and
- the other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

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 management 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 for or prevent a third party from acquiring control of us or changing our Board of Directors and management. These include, but are not limited to, the following:

- classification of the board of directors with staggered terms of three years, which prevents a majority of the incumbent directors from being replaced at a single annual stockholders' meeting;
- 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 the chairman of the board of directors, upon request of stockholders holding at least 20% of the capital stock issued and outstanding, or upon a resolution adopted by, or an affirmative vote of, a majority of the board of directors; and
- requirements that our stockholders comply with advance notice procedures in order to nominate

candidates for election to our Board of Directors or to place stockholders' proposals on the agenda for consideration at meetings of stockholders.

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 of Directors has not exempted us from the business combination statute. Consequently, unless the Board of Directors 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.

Our bylaws also contain a provision exempting us from the "control share acquisition" provisions of the MGCL (Sections 3-701 through 3-709). We can provide no assurance that such provision of our bylaws will not be amended or eliminated in the future. Should this happen, the control share acquisition provisions would become effective and may discourage others from trying to acquire control of us and increase the difficulty of consummating any offer.

Subtitle 8 of Title 3 of the MGCL ("Subtitle 8") permits a Maryland corporation with a class of equity securities registered under the Securities Exchange Act of 1934, as amended (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 rather than until the next annual meeting of stockholders as would otherwise be the case; 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 of Directors 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. Through provisions in our charter and bylaws unrelated to Subtitle 8, we have a classified board, and the number of our directors may be fixed only by the vote of the directors.

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 54% of our outstanding common stock as of March 1, 2015. Included among this 54%, Peter Friedli, the Chairman of the Board of Directors, and certain entities with which he is affiliated, beneficially own approximately 43% of our outstanding common stock as of March 1, 2015. 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.

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.