

# Osprey Medical Preliminary Final Report and Consolidated Financial Statements

**February 26, 2019- Minnesota, United States and Melbourne, Australia** – Osprey Medical (ASX: OSP) today released its Appendix 4E Preliminary Final Report for the full year ended 31 December 2018 and its audited consolidated financial statements, with accompanying notes.

#### **Key financial details**

- Full year sales revenue of US\$2.5M million is 56% higher than in prior corresponding period (FY17: US\$1.6 million)
- Full year net loss of US\$17.5 million, increased 22% from prior corresponding period (FY17: US\$14.3 million)
- Proceeds of A\$14.3 million from a capital raising completed in November 2018
- Cash, deposits at call, and long-term fixed interest term deposits of US\$25.2 million at 31 December 2018 (FY17: US\$32.1 million)

#### **Operational achievements**

- Strong quarterly growth trajectory continued: seventeenth consecutive quarter of sales growth achieved in 4Q18
- 57% year-on-year growth in unit sales and 54% growth in revenue
- Group Purchasing Contract Awards (GPO) covering 50% of US hospitals
- DyeVert featured in ten podium presentations at six major cardiology meetings in 2018
- New product DyeVert Plus EZ launched featuring simplified priming process

#### Strong sales momentum in the United States

Osprey delivered strong unit sales growth in CY2018 with 4Q 2018 representing the Company's 17th consecutive quarter of growth since its inception. Unit sales increased by 57% from CY2017.

Osprey's sales strategy is focused on leveraging U.S. Food and Drug Administration (USFDA) claims received for dye reduction, along with medical society guidelines that call for reduced dye use in Chronic Kidney Disease (CKD) patients to avoid Contrast Induced Acute Kidney Injury (CI-AKI). Osprey has successfully established selling systems and tools to drive product adoption across all territories using these medical society guidelines, as well as a market development approach highlighting the advantages of DyeVert Plus relative to other devices.

#### **GPO-focused sales strategy**

In 2018, Osprey secured contracts with 4 US multi-hospital systems (referred to as GPOs) which cover 50% of heart hospitals in the US. Premier completed a "Burden of Illness" study for the period 2012-2017 that examined charge code data from 749-member hospitals with over 2.8 million CKD patients undergoing angiography procedures (heart imaging and/or stenting). Key findings provide compelling evidence of the growing occurrences, health consequences and the economic burden of AKI, as follows:

- AKI in CKD patient population undergoing angiography increased from 18% to 28% from 2012 to 2017
- Mortality rates post angiography were 61% higher in CKD patients who had AKI events
- Economic burden to all healthcare providers for AKI 90 days post angiography was US\$1.67 billion over the five-year period of the study.

The Premier submission of an abstract to the American College of Cardiology annual scientific sessions (March 2019) has been accepted and a manuscript planned for peer reviewed publication in 2019. The Premier "Burden of Illness" study will add to Osprey's body of clinical evidence supporting the use of DyeVert. The company intends to use the study to drive adoption in GPO targeted hospitals.

#### Podium presentations and publications

A key component of Osprey's commercialisation strategy is to make podium presentations at leading industry events to drive product awareness among the physician community. Osprey's technology was featured in eight podium presentations at key cardiology conferences in CY2018. These included:

- Abstract publication at the National Cardiovascular Data Registry annual meeting (March 2018)
- A presentation at the American College of Cardiology conference (March 2018)
- A presentations at the Society of Cardiovascular Angiography and Interventions conference (May 2018)
- Three presentations at the Cardio-Renal Connections conference (June 2018)
- Two presentations at the Transcatheter Cardiovascular Therapeutics conference (October 2017)

These presentations prominently featured the DyeVert and DyeVert Plus System benefits of >40% dye savings and dye monitoring, without compromised image quality which align with medical society guidelines to minimize and monitor dye in patients with poor kidney function.

# **New product DyeVert Ez**

Osprey secured FDA clearance for and launched the DyeVert EZ in 3Q 2018 which offers a number of enhancements to Osprey's successful DyeVert Plus product including:

- Intuitive, one-way "positive" prime of the system reducing setup time from minutes to seconds relative to DyeVert Plus
- Intuitive and easy-to-remember priming, with fewer system components requiring air removal before use
- Diverted volume of dye can be seen in the collection bag at the end of the procedure

The list price and GPO contract price for DyeVert EZ is the same as the DyeVert Plus. Over time the DyeVert EZ will become the company's primary platform product, given its enhanced convenience and value to the end-use customer.

#### Successful A\$14.3m capital raising

During 4Q 2018, Osprey successfully raised A\$14.3m from existing and new institutional investors at an issue price of A\$0.155, comprising:

- A\$10.0m private placement to leading investment management firm, Allan Gray; and
- A\$4.3m through a non-renounceable entitlement offer to eligible shareholders which closed on 23 November
   2018

Funds raised strengthen Osprey's balance sheet and allows the Company to accelerate its GPO-focused growth strategy.

#### **Outlook**

Osprey remains focused on establishing the DyeVert System as the standard of care for all physicians treating patients at risk of CI-AKI. In 2019 the Company expects sales revenue to continue to grow as the number of hospitals and physicians using DyeVert and DyeVert Plus increases, with increased sales momentum from GPO contracted hospital focus and the adoption of the new DyeVert Ez. The Company will continue to expand its strong and growing network of key opinion leading physicians and hospital centres of excellence, which is expected to provide the framework for accelerating sales over the course of CY 2019 and beyond.

The Appendix 4E and attached audited consolidated financial statements for years ended 31 December 2018 and 2017 have been prepared in U.S. dollars. Also attached is the Report of the Independent Auditor, Baker Tilly Virchow Krause, LLP.

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# **About Osprey Medical (ASX: OSP)**

Osprey Medical's vision is to make heart imaging procedures safer for patients with poor kidney function. The amount of dye (contrast) used during angiographic imaging procedures increases the patient's risk for dye-related kidney damage known as Contrast Induced Acute Kidney Injury (AKI). The Company's core technologies originated from research conducted by Dr David Kaye at Melbourne's Baker Institute. Its proprietary dye reduction and monitoring technologies are designed to help physicians minimize dye usage and monitor the dose of dye real time throughout the procedure. The Company's DyeVert™ Plus System reduces contrast while maintaining image quality in a self-adjusting easy-to-use design that monitors dye usage. Osprey Medical's Board and Management are comprised of experienced and successful personnel with established track records covering medical device development, regulatory approvals, sales and marketing, and mergers-acquisitions. Osprey Medical's advisory board comprises world-recognised experts in heart and kidney diseases.

#### **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Osprey does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Osprey may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

# **Foreign Ownership Restriction**

Osprey's CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of Osprey's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.



# **APPENDIX 4E (RULE 4.3A)**

# PRELIMINARY FINAL REPORT FOR THE YEAR ENDED 31 DECEMBER 2018

# 31 DECEMBER 2018 RESULTS FOR ANNOUNCEMENT TO THE MARKET

(All comparisons to year ended 31 December 2017)

	\$USD	up/down	% movement
Revenue from ordinary activities	\$2,514,117	up	54.18%
Loss after tax from ordinary activities			
attributable to members	(\$17,521,967)	up	20.34%
Loss after tax attributable to members	(\$17,521,967)	up	20.34%

Dividend information			
	Amount per security \$USD	Franked amount per security	Tax rate for franking credit
		\$USD	
Interim dividend	Nil	Nil	N/A
Previous corresponding dividend	Nil	Nil	N/A
Net tangible asset backing			
	31 Dec 2018	31 Dec 2017	
	\$USD	\$USD	
Net tangible asset per share of common stock	\$0.12	\$0.19	
Net tangible asset per CDI	\$0.06	\$0.095	

- Annual financial results: This report is based on the accompanying consolidated 2018 Financial Statements which have been audited by Baker Tilly Virchow Krause, LLP with the Independent Auditor's Report included in the 2018 Financial Statements.
- Changes in control over entities: There were no entities over which control has been gained or lost during 2018.
- **Details of dividends and dividend reinvestment plans:** No dividends have been declared or proposed.
- Details of associates or joint ventures: N/A
- Set of accounting standards used in compiling the report: The audited consolidated financial statement have been prepared in accordance with accounting principles generally accepted in the U.S. (US GAAP) and are denominated in U.S. dollars.
- Details of audit disputes or audit qualification: None

# A commentary on the results for the period:

The net loss for the year increased to \$17,521,967 compared to \$14,336,411 for the previous corresponding period.

Total revenue for the year was \$2,514,117 compared to \$1,630,615 for the previous corresponding period.

Total operating expenses increased to \$18,989,146 from \$14,680,083 because of increased expenses primarily associated with sales and marketing, in relation to the commercialization efforts of the Company.

The Company had cash and cash equivalents of \$25,251,790 at 31 December 2018 compared to \$32,134,848 at 31 December 2017. Net cash flow from financing activities for the year was \$10,186,833.

The Company operated in one segment only during the period and there were no returns to shareholders or share buy backs.

Please refer to our audited consolidated financial statements, with accompanying notes, which are attached hereto.

# **Annual Meeting of Stockholders**

The Annual Meeting of stockholders will be held at *Johnson Winter & Slattery*'s Melbourne office, Level 34, 55 Collins Street, Melbourne, Victoria, Australia on Wednesday, 9 May 2019 at 9.00am Australian Eastern Standard Time (Tuesday, 8 May 2019 at 6.00pm U.S. Central Time).

Minnetonka, Minnesota

# CONSOLIDATED FINANCIAL STATEMENTS

Including Independent Auditors' Report

As of and for the Years Ended December 31, 2018 and 2017

# TABLE OF CONTENTS

Independent Auditors' Report	1
Consolidated Financial Statements	
Consolidated Balance Sheets	2
Consolidated Statements of Operations	3
Consolidated Statements of Shareholders' Equity	4
Consolidated Statements of Cash Flows	5
Notes to Consolidated Financial Statements	6 – 17



#### INDEPENDENT AUDITORS' REPORT

Board of Directors, Audit Committee and Shareholders Osprey Medical, Inc. and Subsidiary Minnetonka, Minnesota and Level 13. 41 Exhibition Street

Level 13, 41 Exhibition Street Melbourne, Victoria 3000, Australia

ARBN: 152 854 923

#### Report on the Consolidated Financial Statements

We have audited the accompanying consolidated financial statements of Osprey Medical, Inc. and Subsidiary, which comprise the consolidated balance sheets as of December 31, 2018 and 2017, and the related consolidated statements of operations, shareholders' equity, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

#### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Osprey Medical, Inc. and Subsidiary as of December 31, 2018 and 2017 and the results of their operations and cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Minneapolis, Minnesota February 26, 2019

Baker Tilly Virchaw & rause, LLP

Baker Tilly Virchow Krause, LLP trading as Baker Tilly is a member of the global network of Baker Tilly International Ltd., the members of which are separate and independent legal entities.

# CONSOLIDATED BALANCE SHEETS As of December 31, 2018 and 2017

ASSETS		
	2018	2017
CURRENT ASSETS  Cash and cash equivalents Accounts receivable Prepaid expenses Inventory Total Current Assets	\$ 25,251,790 392,634 291,378 771,842 26,707,644	\$ 32,134,848 310,103 144,446 762,185 33,351,582
PROPERTY AND EQUIPMENT Office and computer equipment Laboratory equipment Furniture and fixtures Leasehold improvements Less: Accumulated depreciation Net Property and Equipment	441,398 1,070,551 46,103 172,998 (1,000,281) 730,769	374,215 1,001,848 46,103 - (738,853) 683,313
OTHER ASSETS Intangible assets, net of accumulated amortization of \$143,704 and \$131,208 as of December 31, 2018 and 2017, respectively Other asset Total Other Assets	83,307 12,250 95,557	95,803 12,250 108,053
TOTAL ASSETS	\$ 27,533,970	<u>\$ 34,142,948</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES Accounts payable Accrued payroll and related Accrued vacation Total Current Liabilities	\$ 875,805 808,123 169,183 1,853,111	\$ 557,464 1,062,681 159,660 1,779,805
LONG-TERM LIABILITIES Accrued rent Other accrued liabilities Total Liabilities	6,987 139,278 1,999,376	4,330 - 1,784,135
SHAREHOLDERS' EQUITY  Preferred stock, \$0.0001 par value; 20,000,000 authorized shares; none issued and outstanding as of December 31, 2018 and 2017  Common stock, \$0.0001 par value; 630,000,000 authorized shares; 215,898,685 and 169,754,103 shares issued and outstanding as of December 31, 2018 and 2017, respectively  Additional paid-in capital  Accumulated deficit  Total Shareholders' Equity	21,590 122,271,893 (96,758,889) 25,534,594	16,975 111,578,760 (79,236,922) 32,358,813

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

\$ 34,142,948

\$ 27,533,970

# CONSOLIDATED STATEMENTS OF OPERATIONS For the Years Ended December 31, 2018 and 2017

	2018		2017
SALES	\$ 2,514,117	\$	1,630,615
COST OF SALES	 1,384,277		1,393,722
Gross Profit	 1,129,840		236,893
OPERATING EXPENSES Sales and marketing General and administrative Clinical and regulatory Research and development Total Operating Expenses	 9,990,594 3,445,549 1,917,548 3,635,455 18,989,146		7,113,767 3,100,607 1,239,023 3,226,686 14,680,083
Operating Loss	 (17,859,306)		(14,443,190)
OTHER INCOME Other income Net Other Income	 344,320 344,320	_	110,253 110,253
Loss Before Taxes	(17,514,986)		(14,332,937)
Income tax provision	 6,981		3,474
NET LOSS	\$ (17,521,967)	\$	(14,336,411)
EARNINGS PER SHARE:  Basic and diluted loss per common share Basic and diluted weighted average shares outstanding	\$ 0.10 177,444,867	\$	0.10 142,497,786

# CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY For the Years Ended December 31, 2018 and 2017

	Commo	on Sto	ock		Additional Paid-in	Accumulated	S	Total Shareholders'
	Shares		Amount	Capital		Deficit	_	Equity
BALANCES, December 31, 2016	128,869,627	\$	12,887	\$	86,524,388	\$ (64,900,511)	\$	21,636,764
Issuance of common stock at \$0.62 per share, net of issuance costs of \$1,156,773	40,625,114		4,062		24,332,244	_		24,336,306
Exercise of stock options	259,362		26		113,155			113,181
Stock-based compensation expense	-		-		608,973	-		608,973
2017 net loss			<u>-</u>	_		(14.336.411)	_	(14.336.411)
BALANCES, December 31, 2017	169,754,103		16,975		111,578,760	(79,236,922)		32,358,813
Issuance of common stock at \$0.22, per share, net of issuance costs of \$136,247	46,144,582		4,615		10,182,218			10,186,833
Stock-based compensation expense	-		-		510,915	-		510,915
2018 net loss				_		(17.521.967)	_	(17.521.967)
BALANCES, December 31, 2018	215,898,685	\$	21,590	\$	122,271,893	\$ (96,758,889)	\$	25,534,594

# CONSOLIDATED STATEMENTS OF CASH FLOWS For the Years Ended December 31, 2018 and 2017

		2018		2017
CASH FLOWS FROM OPERATING ACTIVITIES	•	(47 504 007)	•	(44,000,444)
Net Loss Adjustments to reconcile net loss to net cash flows from operating activities	\$ (	(17,521,967)	\$	(14,336,411)
Depreciation		261,428		185,376
Amortization		12,496		12,496
Stock-based compensation expense		510,915		608,973
Changes in operating assets and liabilities		2.0,2.0		,
Accounts receivable		(82,531)		(175,157)
Prepaid expenses		(146,932)		(82,637)
Inventory		(9,657)		(501,249)
Accounts payable		318,341		141,921
Accrued payroll and related		(254,558)		275,862
Accrued rent		2,657		(16,842)
Other accrued liabilities		139,278		-
Accrued vacation		9,523		41,430
Net Cash Flows from Operating Activities		<u>(16,761,007)</u>	_	(13,846,238)
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property and equipment		(308,884)		(321,840)
Net Cash Flows from Investing Activities		(308.884)	_	(321.840)
Ü		(000,00.)		(02.10.0)
CASH FLOWS FROM FINANCING ACTIVITIES				
Issuance of common stock, net of issuance costs		10,186,833		24,336,306
Proceeds from exercise of stock options		<u>-</u>		113,181
Net Cash Flows from Financing Activities		10,186,833		24,449,487
Net Change in Cash and Cash Equivalents		(6,883,058)		10,281,409
CACHAND CACH FOLINAL FAITO B		00.404.040		04.050.400
CASH AND CASH EQUIVALENTS - Beginning of Year		32,134,848	-	21,853,439
CASH AND CASH EQUIVALENTS - END OF YEAR	\$	25,251,790	\$	32,134,848
ONOTI AND ONOTI ENGINALERITO - END OF TEAM	Ψ	20,201,730	Ψ	02,107,070
SUPPLEMENTAL CASH FLOW DISCLOSURES				
Cash paid for income taxes	\$	6.981	\$	3.474
Caon paid for moorifo taxoo	Ψ	0,001	Ψ	0,717

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

## **NOTE 1 - Summary of Significant Accounting Policies**

#### Nature of Operations

Osprey Medical, Inc. ("Osprey", "Osprey Medical" or the "Company") is a US based, commercial stage company focused on protecting patients from the harmful effects of X-ray dye (contrast) used during commonly performed angiographic imaging procedures. Osprey's mission is to improve outcomes in patients with Chronic Kidney Disease (CKD) and at high risk of acquiring Contrast-Induced Acute Kidney Injury (AKI). Patients with AKI experience long term and costly side effects from this disease. The incidence of AKI also has a negative economic impact on the health care providers caring for these patients. Osprey Medical is committed to making angiography safer for patients suffering from CKD, improving outcomes, and reducing economic impact.

The Company's products are designed to reduce the amount of contrast injected into patients during standard cardiovascular and peripheral procedures (angiogram and stenting). Published literature indicates approximately 25% of patients undergoing standard cardiovascular procedures have preexisting CKD and are at high risk of further kidney damage due to AKI. Cardiology and Radiology clinical society guidelines strongly recommend reducing the risk of AKI by screening patients for risk of kidney disease, adequately hydrating hi-risk patients pre- and post-procedure, minimizing the amount of contrast delivered to the patient, and monitoring in real time the amount of contrast delivered during the angiography procedure.

Osprey Medical's core technologies originated from research conducted at Melbourne's Baker IDI Heart and Diabetes Institute. Its proprietary contrast reduction and monitoring technologies are designed to help physicians minimize and track contrast volumes administered to patients. The Company's DyeVert™ System reduces contrast while maintaining image quality in a self-adjusting easy-to-use design. The system's monitoring component allows for real-time contrast monitoring throughout the procedure and the ability to establish maximum contrast thresholds for each patient. The monitoring system displays total contrast administered to the patient and the amount saved during the procedure.

Following successful clinical trials, the Company obtained European Regulatory approval (CE Mark), TGA approval, and United States of America Food and Drug Administration ("FDA") clearance for the AVERT™, AVERT Plus, and DyeVert System. The Company received FDA clearance for medical claims of contrast savings, image quality and reflux reduction for its products

The company commenced its commercial strategy in 2015 and has since built a sales organization focused on commercializing its DyeVert Systems to hospitals throughout the United States. As of December 31, 2018, the company has a VP of Sales, 3 Sales Directors, 20 territory managers, and 7 clinical specialists.

Osprey Medical's patent portfolio comprises of 16 issued US patents, 26 issued international patents; 14 pending US patent applications, and PCT filings resulting in 20 National Stage Applications in the European Union (Germany, France and Great Britain), Japan and Australia.

On October 30, 2007, the Company formed a wholly-owned Australian subsidiary with the name Osprey Medical Pty. Ltd. (OM Pty) for the purpose of conducting research on future products. The subsidiary began operations in early 2008.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# NOTE 1 - Summary of Significant Accounting Policies (cont.)

## Principles of Presentation

The consolidated financial statements include the accounts of the Company's wholly-owned Australian subsidiary, OM Pty. All intercompany accounts and transactions have been eliminated in consolidation.

The US dollar is the functional currency of OM Pty, and as a result, all currency gains and losses are reflected in operations. Currency gains and losses include realized amounts on transactions, and unrealized amounts related to translating accounts from local currency to the functional currency, with translation accomplished using the current rate method.

In its consolidated statements of operations, the Company segregates its operating expenses into four categories that provide useful information to both management and Company shareholders.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

# Cash and Cash Equivalents

Cash and cash equivalents include short-term investments with maturities of three months or less from their date of purchase. The Company maintains cash balances that exceed federally insured limits; however, it has not incurred losses on such amounts to date.

#### Accounts Receivable

The Company grants credit to customers in the normal course of business and generally does not require collateral or any other security to support amounts due. Customer accounts with balances outstanding longer than the contractual terms are considered past due. The Company records accounts receivable at the original invoice amount less an estimate made for doubtful receivables based on periodic reviews of all outstanding amounts. The Company determines the need for an allowance for doubtful accounts by considering a number of factors, including length of time accounts receivables are past due, customer financial condition and ability to pay the obligation, historical and expected credit loss experience, and the condition of the general economy and the industry as a whole. It is the Company's policy to write-off accounts receivable when deemed uncollectible. There was no allowance for doubtful accounts as of December 31, 2018, and 2017.

#### Inventories

Inventories are stated at lower of cost (using the first-in, first-out method) or net realizable value, and are as follows as of December 31:

	 2018	 2017
Raw materials	\$ 399,589	\$ 563,121
Finished goods	 372,253	199,064
Total	\$ 771,842	\$ 762,185

The Company has invested in its manufacturing operations to support future sales. The Company is not currently operating at full capacity. Charges related to excess capacity are included as current period charges to cost of sales and are not capitalized into inventory.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# NOTE 1 - Summary of Significant Accounting Policies (cont.)

## Property and Equipment

Property and equipment are recorded at cost, and depreciation and amortization are provided on the straight-line method over the estimated useful lives of the assets:

	Years
Office and computer equipment	3
Furniture and fixtures	7
Laboratory equipment	5
Leasehold Improvements	5

Maintenance and repairs are charged to expense as incurred. Depreciation expense on property and equipment was \$261,428 and \$185,376 for the years ended December 31, 2018 and 2017, respectively.

#### Intangible Assets

Intellectual property acquired for consideration is recorded either as research and development expense or as intangible assets, as appropriate to the use of the property. Intellectual property that has multiple future uses is capitalized when acquired, and single use property is expensed as research and development. The Company's recorded intangible assets are comprised entirely of patent applications acquired from V-Kardia Pty. (VK Pty) for which there were multiple future uses. At acquisition of these assets there was a difference between the value of the asset acquired and its tax basis, and the Company increased the assigned value of the asset acquired by the amount of the related deferred tax liability. The Company amortizes intangible assets on a straight-line basis over their expected economic lives, which is equivalent to the time from acquisition through expiration of the patents expected to be issued from the acquired patent applications. The intangible assets acquired in June, 2007 are expected to have a life of approximately 18 years from the date of acquisition.

# Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC"), Topic 606, *Revenue from Contracts with Customers*, which the Company adopted effective January 1, 2018. Accordingly, the Company recognizes revenue when its customers obtain control of its products, which occurs at a point in time, generally upon delivery to the customer. The amount recognized as revenue is the invoiced price adjusted for variable consideration, if any, in exchange for goods delivered. All revenue is recognized when the Company satisfies its performance obligations. The Company does not have any contract assets or liabilities as of December 31, 2018 or 2017 and the adoption of ASC Topic 606 did not have an impact on the financial statements.

# Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset may not be fully recoverable. An impairment loss would be recognized when the estimated future cash flow from the use of the asset are less than the carrying amount of that asset. To date, there have been no such losses.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# NOTE 1 - Summary of Significant Accounting Policies (cont.)

## Lease Expense

The Company recognizes rental expense and tenant improvement allowances for operating leases on a straight-line basis over the term of the lease.

#### Research and Development Costs

Research and development costs are charged to expense as incurred. The Company has acquired licenses to intellectual property that do not have multiple uses and records such acquisition costs as research and development as incurred. Consideration for such intellectual property includes current and future payments of cash, issuance of common stock and warrants to acquire common stock.

#### Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are determined based on the differences between financial reporting and tax bases of the assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce net deferred tax assets when it believes it is more likely than not that all or part of its deferred tax assets will not be realized.

#### Stock-Based Compensation

The Company accounts for stock-based payment transactions when it receives employee or supplier goods and services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments using a fair-value-based method. The Company uses the Black-Scholes-Merton (BSM) option pricing model to determine the fair value of stock-based awards. The fair value of stock-based payment is recognized over the requisite service period.

#### Issuance of Stock

The Company issues new shares of stock upon the exercise of stock options, warrants and converted instruments.

#### Going Concern

The financial statements are prepared on a going concern basis. Management evaluates the ability for the entity to continue as a going concern for at least twelve months from the date the financial statements are issued. In the event management concludes that there is substantial doubt regarding the Company's ability to continue as a going concern, the assumption is emphasized in the consolidated financial statement disclosures, including management's plan to mitigate the conditions that cause substantial doubt. If substantial doubt regarding the Company's ability to continue as a going concern is alleviated, the Company provides disclosures regarding the conditions or events that raised substantial doubt, management's evaluation of the significance of those conditions or events and management's plans that alleviated the substantial doubt.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

#### **NOTE 1 - Summary of Significant Accounting Policies** (cont.)

## Recent Accounting Pronouncements

In May 2014, August 2015, March 2016, April 2016 and May 2016, the Financial Accounting Standards Board ("FASB") issued amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The Company adopted this new standard on January 1, 2018, utilizing the modified retrospective approach. There was no impact to the amount or timing of revenue that the Company had recognized in prior periods.

In February 2016, the FASB issued updated guidance to improve financial reporting about leasing transactions. This guidance will require organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. This guidance is effective for the Company's annual periods beginning January 1, 2019, and for quarterly periods thereafter. The Company is evaluating the impact that the adoption of this standard will have, if any, on its financial statements and disclosures but anticipates recognizing additional right to use assets and lease obligations on its consolidated balance sheet.

#### Subsequent Events

For the year ended December 31, 2018, the Company has evaluated, for potential recognition and disclosure, events that occurred prior to the issuance of the consolidated financial statements for the years ended December 31, 2018 on February 26, 2019.

#### NOTE 2 – Liquidity

The Company has an accumulated deficit and has not generated significant revenues since inception. The Company expects that its expenses will exceed its revenues at least up to, and likely beyond, the point at which the Company is able to generate significant revenues from its approved products. The Company expects to have enough working capital to operate for at least the next twelve months beyond February 26, 2019.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

#### **NOTE 3 - Fair Value Measurements**

Generally, fair value is determined on the exchange price which would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. The Company discloses each major asset and liability category measured at fair value on either a recurring or nonrecurring basis and establishes a three tier fair value hierarchy which prioritizes the inputs used in fair value measurements. The three tier hierarchy for inputs used in measuring fair value is as follows:

- > Level 1 Observable inputs such as quoted prices in active markets
- > Level 2 Inputs other than the quoted prices in active markets that are observable either directly or indirectly
- > Level 3 Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis:

As of December 31, 2018:	Total	Level 1	 Level 2	Level 3
Cash and cash equivalents - money market securities	\$ 15,016,252	\$ 15,016,252	\$ -	\$ -
As of December 31, 2017:  Cash and cash equivalents - money market securities	\$ Total 28,674,801	\$ Level 1 28,674,801	\$ Level 2	\$ Level 3

#### **NOTE 4 - Leases**

In March 2014, the Company signed an amendment to the lease for additional square footage. The lease term, as amended expired in March 2018. In April 2018, the Company signed an amended lease for their current location in Minnetonka, Minnesota. The lease term with substantial leasehold improvements, as amended expires in May 2023, and contains no extensions or renewal options. The Company is currently negotiating an extended lease provision. The monthly payments ranging from \$12,284 to \$14,241 for the lease.

Rent expense was \$92,142 and \$91,525 for the years ended December 31, 2018 and 2017, respectively. Rent is recorded on a straight-line recognition basis and the difference is recorded as an accrued long-term liability.

Under the terms of the lease for office space, the Company paid monthly base rent and was additionally responsible for its pro rata share of estimated operating expenses, which include utilities, taxes, maintenance, repair, and insurance costs. The minimum remaining lease commitments under the terms of the noncancelable building lease for the years ending December 31:

2019	\$ 150,728
2020	155,250
2021	159,908
2022	164,704
2023	 69,960
Total	\$ 700,550

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# **NOTE 5 - Employee Benefits**

The Company provides a 401k plan as a benefit to its employees. In April 2018, the Company started a 5% match of qualified payments under the 401K plan. Under the plan, eligible employees may contribute amounts through payroll deductions supplemented by employer contributions for investment in various investments specified in the plan. Company contributions to the plan were \$170,897 and \$0 for the years ended December 31, 2018 and 2017, respectively.

# **NOTE 6 - Intangible Assets**

The Company received a license at inception from its then parent company, VK Pty, to certain intellectual property. That license became inoperative when VK Pty assigned its intellectual property to the Company on June 21, 2007, in advance of preferred stock financing from CM Capital Investments (CMCI). The assignment was done in exchange for issuing 348,098 shares of the Company's common stock to VK Pty, valued at \$.50 per share. As a result of these transactions, during 2007, the Company expensed as research and development the full \$14,600 of the original intangible asset value and an additional \$4,443 of value related to the deferred tax liability assigned to the initial license. The Company capitalized \$174,049 of purchased value and an additional \$52,962 related to the corresponding deferred tax liability as an intangible asset, reflecting the value of the acquired intellectual property.

The intellectual property is expected to have a useful life equal to the life of the underlying patent applications. Such life will extend, on average, 18 years from 2007 to 2025. Amortization is recorded on a straight-line basis beginning at acquisition date, resulting in amortization expense of \$12,496 for both years ended December 31, 2018 and 2017. Amortization expense will approximate \$12,496 in each of the next five years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# **NOTE 7 - Income Taxes**

Osprey Medical is a C corporation under the U.S. Internal Revenue Code.

The Company incurred income tax expense of \$6,891 and \$3,474 for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, and 2017, the Company has recorded a valuation allowance to offset its net deferred tax assets due to uncertainty surrounding realization of the net deferred tax assets.

The Company has accumulated net operating losses to be carried forward to future years in the amount of \$90,441,356 applicable to income subject to federal income tax and \$40,952,229 applicable to income subject to state income tax as of December 31, 2018. These state carryforwards begin to expire in 2023. Utilization of these net operating losses to offset future taxable income may be limited.

Income tax expense (benefit) consists of the following:

		2018	2017
Current: Federal	\$	_	\$ -
State Foreign	Ψ	6,891	3,474
i dicigii		6,891	3,474
Deferred:			
Federal		4,224,000	5,263,000
State		580,000	-
Foreign		<u> </u>	
		4,804,000	5,263,000
Deferred tax asset valuation allowance		(4,804,000)	(5,263,000)
Total provision	\$	6,891	\$ 3,474

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# NOTE 7 - Income Taxes (cont'd)

Changes in tax laws and rates may affect recorded deferred tax assets and liabilities and our effective tax rate in the future. On December 22, 2017, the U.S. President signed into law the Tax Cuts and Jobs Act (the "Act"), which enacted tax law changes largely effective for tax years beginning after December 31, 2017. The Act reduces the corporate tax rate to 21%, effective January 1, 2018, for all corporations. The Company has revalued its deferred tax assets and liabilities as of December 22, 2017. The deferred tax assets and liabilities are fully offset with a valuation allowance, and therefore the Company did not recognize any income tax expense related to the revaluation.

Income tax expense differs from the amount computed at the statutory federal income tax rate of 34% due principally to nondeductible expenses, different rates for foreign jurisdictions and the recognition of a valuation allowance against the net deferred tax asset.

Significant components of deferred tax assets and liabilities as of December 31 are as follows:

	 2018		2017	
Deferred tax assets:				
Net operating loss carryforwards	\$ 21,692,000	\$	17,814,000	
Research and development credit	1,261,000		371,000	
Organization costs	1,000			
Accrued vacation	41,000		34,000	
Deferred rent	10,000		1,000	
Stock-based compensation expense	 108,000		85,000	
	 23,113,000		18,306,000	
Deferred tax liability:				
Intangible assets	 (48,000)		(45,000)	
-	 (48,000)		(45,000)	
Net deferred tax asset	23,065,000		18,261,000	
Valuation allowance	 (23,065,000)		(18,261,000)	
	\$ -	\$	- -	

The valuation allowance for deferred tax assets changed by \$4,804,000 and \$(5,263,000) for the years ended December 31, 2018 and 2017, respectively.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority.

The Company is not currently under examination by any taxing jurisdiction. In the event of any future tax assessments, the Company has elected to record the income taxes and any related interest and penalties as income tax expense on the Company's statement of operations.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# **NOTE 8 - Common Stock and Preferred Shares**

During the year ended December 31, 2018, there were no options exercised. During the year ended December 31, 2017, options exercised resulted in the Company issuing 259,362 shares of common stock for proceeds of \$113,181. The intrinsic value of the options exercised as of December 31, 2017 was \$67,012.

In August 2017, the Company authorized an additional 450,000,000 shares of common stock resulting in a total amount authorized of 630,000,000.

In November 2018, the Company completed a private offering on the Australian Securities Exchange of 32,258,065 shares of common stock at a price to the public of \$0.22 per share. In addition, in October 2018, a pro rata non-renounceable Entitlement Offer was offered to qualified shareholders of record. Under the Entitlement Offer, 13,886,517 shares of common stock were issued in November 2018 at a price of \$0.22 per share. As a result of the total financing, the Company raised approximately \$10,323,080 in gross proceeds, before issuance costs of approximately \$136,247.

In August and September 2017, the Company completed a private offering on the Australian Securities Exchange of 27,732,038 shares of common stock at a price to the public of \$0.62 per share. In addition, in September 2017, a pro rata non-renounceable Entitlement Offer was offered to qualified shareholders of record of 12,893,076 shares of common stock at a price to the public of \$0.62 per share. As a result of the total financing, the Company raised approximately \$25,500,000 in gross proceeds, before issuance costs of approximately \$1,200,000.

As of December 31, 2018, and 2017, respectively, the common shares outstanding were 215,898,685 and 169,754,103. As of December 31, 2018, and 2017, there are no preferred shares outstanding.

# NOTE 9 – Weighted Average Shares Calculation

Basic loss per share is computed by dividing net loss by the weighted average shares outstanding during the reporting period. Diluted loss per share is computed similarly to basic loss per share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of stock warrants and options, if dilutive. Diluted loss per share does not include any of these dilutive effects in its calculation. The number of additional dilutive shares is calculated by assuming that outstanding stock options were exercised and that the proceeds from the exercise were used to acquire shares of common stock at the average market price during the reporting period.

Shares used in the loss per share computations for the years ended December 31, 2018 and 2017 are as follows:

	2018	2017
Weighted average common shares outstanding – basic	177,444,867	142,497,786
Dilutive effect of stock option and warrants	<u>-</u> _	<u>-</u>
Weighted average common shares outstanding – diluted	<u>177,444,867</u>	142,497,786

As of December 31, 2018 and 2017, stock options shares of 13,564,956 and 11,138,073, respectively, were not included as their effect is anti-dilutive due to the loss for the years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# **NOTE 10 - Stock-Based Compensation**

The Company had a stock incentive plan (the 2006 Plan) that provided for the issuance of incentive and non-qualified stock options to employees and directors, for the purpose of encouraging key officers, directors, employees, and consultants of the Company to remain with the Company and devote their best efforts to the business of the Company. The 2006 Plan expired in 2016, and 7,554,573 shares then outstanding remain available for exercise as of December 31, 2018. On August 29, 2016, the Company's stockholders approved a new stock option plan (the 2016 Plan) with the same directive as the old plan. Under the 2016 Plan, incentive stock options must be granted at exercise prices not less than 100% of the fair value of the Company's stock as of the grant date. If incentive options are granted to persons owning more than 10% of the voting stock of the Company, the Plan provides that the exercise price shall not be less than 110% of the fair value of the Company's stock as of the grant date. These options have exercise and vesting terms established by the Option Committee of the Company's Board of Directors at the time of each grant, but in no event are the options exercisable after ten years from the date of grant. The options granted are subject to time based vesting ranging from immediate vesting to vesting 48 months after the date of grant. The Board of Directors approved an increase in the 2016 Plan of 2,575,750 shares in May 2018. The Company has reserved 7,178,236 shares of common stock for issuance under the 2016 Plan, as of December 31, 2018. As of December 31, 2018, options issued under the 2016 plan were 6,010,383.

The following table presents the weighted average assumptions used to estimate the fair values of the stock options granted to employees and nonemployees in the periods presented, using the BSM option pricing formula: The risk free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The expected life and expected volatility are based on the average reported lives and volatilities of our company.

	Year Ended	Year Ended
	<u>December 31,2018</u>	December 31,2017
Risk-free interest rate	.69% - 2.84%	1.23% - 2.15%
Expected volatility	78.00% - 90.88%	69.67% - 71.80%
Expected life (in years)	5.92	4.00
Dividend yield	0.00%	0.00%
Weighted-average estimated fair value of options granted	\$0.21	\$0.29

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS As of and for the Years Ended December 31, 2018 and 2017

# **NOTE 10 - Stock-Based Compensation** (cont'd)

The following table summarizes the activity for outstanding employee and non-employee stock options:

	Weighted-Average Remaining			
		Weighted-Average	Contractual Term	Aggregate
	Number of Shares	Exercise Price	(Years)	Intrinsic Value
Balance as of December 31, 2016	10,297,435	\$ 0.71	6.3	
Granted	1,841,500	0.61		
Exercised	(259,362)	(0.44)		
Expired	(741,500)	(0.79)		
Balance as of December 31, 2017	11,138,073	0.71	6.0	
Granted	2,537,883	0.29		
Expired	(111,000)	(0.53)		
Balance as of December 31, 2018	13,564,956	\$ 0.64	5.78	\$ -
Exercisable as of December 31, 2018	8,225,791	\$ 0.79	5.53	<u> - </u>

The aggregate intrinsic value is calculated as approximately the difference between the weighted average exercise price of the underlying awards and the share fair value as of December 31, 2018.

The Company recognized stock-based compensation expense related to stock options of \$510,915 and \$608,973 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, \$1,082,166 of total unrecognized compensation cost related to stock options is expected to be recognized over a weighted average period of 1.87 years. To the extent the forfeiture rate is different than anticipated stock-based compensation related to these awards will be different from the Company's expectations.