

# Oncology Venture

## Interim Report 2017-01-01 – 2017-12-31

*Oncology Venture Sweden AB (publ) | 559016-3290*

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*The Company is listed on AktieTorget (ticker: OV)*

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*The Management Board and Chief Executive Officer of Oncology Venture Sweden AB hereby submit a report for the accounting year 2017. "Oncology Venture Sweden AB" refers to Oncology Venture Sweden AB with corporate identification number 559016-3290. "The Company" or "Oncology Venture" refers to the group, that is Oncology Venture Sweden AB and its subsidiary company Oncology Venture ApS (100% owned by Oncology Venture), 2X Oncology (92% by Oncology Venture) and OV-SPV2 ApS (40% owned by Oncology Venture).*

## **Summary of communique on financial report**

### **Twelve months (2017-01-01 – 2017-12-31)**

- The Group's net turnover increased to 1,996 (1,305) KSEK.
- The Group's result after tax decreased to -56,547 (-33,543) KSEK.
- The Group's cash and bank assets decreased to 11,977 (18,872) KSEK.
- The Group's result per share decreased to -5.20 (-1.95) SEK.
- Its solidity increased to 82,5 (78.8) %.

### **Fourth quarter (2017-10-01 – 2017-12-31)**

- The Group's net turnover increased to 0 (1,169) KSEK.
- The Group's result after tax increased to -22,527\* (-18,618) KSEK.
- The Group's result per share increased to -2.07 (-1.85) SEK.

*The Group's result per share: The result for the period divided by the average number of shares. Total number of shares as of 31 December 2017 increased to 10,980,573. Average number of shares for the period is 10,944,862.30.*

*Amount within brackets: Comparable period in the previous year.*

*Solidity: Equity divided by total capital.*

*\*The result was mainly influenced by operating costs. These mainly consisted of one-off production costs of approximately 7 000 KSEK (mainly regarding manufacturing of Irofulven), 4 000 KSEK regarding screening and clinical site costs and 3 300 KSEK regarding costs for clinical research operations, mainly regarding preparation of Phase 2 studies. 5 400 KSEK are referred to costs borne by 2X Oncology, whose accounts are incorporated into Oncology Venture's group accounts.*

### **Important events during 2017**

- On 22 December Oncology Venture advises that the Company has been given approval by the Danish Ethics Committee and Health Authority (DHMA) for its application to implement a phase-2 trial of Irofulven in patients with castration and docetaxel-resistant prostate cancer.
- On 15 December, Oncology Venture advises that a publication with the title "*Drug response prediction in high-risk multiple myeloma*" will be published in the scientific journal "Gene". The printed version is expected to be made available in January 2018. In the publication it is demonstrated that MPI's drug response predictor - DRP® - can predict sensitivity to melfalan (extended progression-free survival, PFS) and bortezomib (extended PFS and with a better response rate, RR).
- On 14 December, Oncology Venture advises an updated timetable for obtaining results for the response prediction in patients for a non-publicised small molecule TKI inhibitor from Novartis Pharma AG.
- On 30 November, Oncology Venture advises that the Company's Board of Directors have decided, subject to the approval of an extraordinary annual general meeting, to implement a representative subscription of a maximum 2,745,143 shares at an subscription price of 16.30 SEK per share. The fully subscribed new issue will make Oncology Venture around MSEK 44.7 before issuing costs.
- On 21 November, Oncology Venture advises that the dose of 75mg + 75mg per patient on day 1 and 8 in a three-week scheme has been confirmed as being safe and is therefore approved by the committee for safety data that had recommended the dose (RD) for future treatments with LiPlaCis®. It was also advised that the rate of the patient recruitment for the ongoing phase-2 part of the trial of metastatic breast cancer involving treatment with LiPlaCis® had been accelerated over recent months and had now been found to be adequate.

- On 16 November, Oncology Venture advises that the Company had reached an agreement with one the major investors in OV-SPV2 ApS to extend the option to repurchase shares in OV-SPV2, which owns the rights to the TKI inhibitor from Novartis. The option will be extended by six months, up until 1 June 2018.
- On 7 November the number of shares in Oncology Venture increase after Medical Prognosis Institute A/S ("MPI") in March 2017 used 100,000 of the 302,243 warrants that MPI acquired in payment for the expanded three-year exclusive licence for MPI's Drug Response Prediction technology, DRP®. The new number of shares in Oncology Venture is hence 10,977,007.
- On 27 October, the Company advises that a phase-2 protocol for Irofulven for castration and docetaxel-resistant prostate cancer had been submitted to the Danish Ethics Committee and Health Authority.
- On 23 October the Company publishes a pipeline and business update, describing the status of its ongoing projects.
- Oncology Venture advises on 29 September that 12 patients with metastatic breast cancer had been successfully recruited to the phase 2 part of the clinical trial of LiPlaCis® for metastatic breast cancer. Oncology Venture has previously advised that the Company was expecting to recruit between 12 and 15 patients up to and including Q3 2017.
- On 19 September, Oncology Venture advises that early data from an ongoing phase 1/2 trial of LiPlaCis® show response and clinical effects in patients with metastatic breast cancer who are difficult to treat.
- On 23 August, Oncology Venture publishes an update of its pipeline.
- Oncology Venture advises on 9 August that the Company has made an accurate DRP® prediction of the results of treatment in patients treated with 2X-121, the recently licensed PARP inhibitor from Eisai Inc.
- On 19 July Oncology Venture and Novartis Pharma AG enter into an agreement on an option for an exclusive licence for a tyrosine kinase inhibitor in clinical phase 3.
- On 7 July Oncology Venture and Eisai Inc. enter into an exclusive global licence agreement for the clinical oncological drug candidate PARP Inhibitor E7449/2X-121. E7449 has already shown a good treatment effect in phase 1.
- Oncology Venture advises on 6 July that the Danish Health Authority and Medicines Agency and the Ethics Committee permit the inclusion of patients with metastatic breast cancer in the phase 2 trial of LiPlaCis® as early as after the patients' second line of treatment. A LiPlaCis® side-effects profile also enables more vulnerable patients with low levels of blood platelets and patients with an impaired liver function to be included in the trial.
- On 27 June, Oncology Venture advises that data from the ongoing phase 1/2 trial show that the tumour response of LiPlaCis® in clinical practice can be predicted by the Company's Drug Response Predictor (DRP®) whatever the type of tumour, which includes breast cancer.
- On 8 June, Oncology Ventures spinout, 2X Oncology Inc., receives an American IND for 2X-111, a liposomal doxorubicin for the treatment of breast and brain cancer.
- DRP® data for epirubicin for breast cancer are presented as a poster on the poster session "Breast Cancer – Metastatic" at ASCO's (American Society of Clinical Oncology) annual meeting on 4 June 2017 in Chicago, Illinois, USA.
- Oncology Venture advises 31 May that the first patient has been included in the phase 1/2 trial of APO010 for the treatment of multiple myeloma (MM).
- Oncology Venture is informed on 29 May by the US Patent Office that they intend to approve a patent application for a Drug Response Predictor (DRP®) for the Company's cancer drug Irofulven.

- The DRP® data for epirubicin for breast cancer is published on ASCO's (American Society of Clinical Oncology) website. DRP® was significantly associated with progression-free survival (PFS) in a cohort of 137 patients with metastatic breast cancer.
- On 8 May the annual general meeting is held in the Company. A communique containing the decisions that were made is available on the Company's website.
- On 6 April, 2X Oncology expands its management group and appoints George O. Elston as CEO, while Marie Foegh continues as CMO within the company.
- Oncology Venture advises on 5 April that the Company has implemented a representative subscription, which makes the Company approx. 33.7 MSEK before subscription costs.
- On 28 March Oncology Venture enters into an exclusive global licence agreement for 2-BBB Medicines BV's leading phase-2 product 2B3-101 – now called 2X-111 – for the treatment of glioblastoma (primary brain cancer).
- On 24 March, Oncology Venture and Eisai Inc. enter into an agreement according to which Oncology Venture will develop companion diagnostics by means of its DRP™ technology for a drug candidate from Eisai Inc's oncological portfolio. The intention is to evaluate Oncology Venture's interest in an in-licensing of the drug for further clinical development in 2X Oncology.
- On 21 March the Danish Medicines Agency (DHMA) approves the focused trial of APO010 in patients with multiple myeloma.
- Oncology Venture receives on 8 March around 1,000,000 SEK by using subscription warrants of the 2019 series.
- An extraordinary annual general meeting is held in Oncology Venture on 1 March. A communiqué from the extraordinary annual general meeting is available at the Company's and AktieTorget's ([www.aktietorget.se](http://www.aktietorget.se)) respective websites.
- Oncology Venture advises on 21 February that the Company has developed a new version of LiPlaCis® that can be kept at 2-8°C. This product has been successfully produced and passed all quality controls.
- Oncology Venture publishes on 31 January a status update regarding the Company's pipeline covering three products in Oncology Venture, two signed term sheets, a term sheet under negotiation in 2X Oncology and an agreed term sheet in OV-SPV2 ApS.
- Oncology Venture advises on 24 January that DRP® successfully predicts the effect of four breast cancer drugs from Personalized Medicine.
- Oncology Venture advises on 19 January that the LiPlaCis® project is granted a total of approx. 963,000 euro (approx. 9.1 MSEK) via the EUROSTARS programme for the further development of the project. Moreover, the public contribution releases private investment funds of approx. 950,000 euro (approx. 9.0 MSEK) from the Company's partner Smerud Medical Research International AS. In total, the contribution received for the LiPlaCis® programme amounts to approx. 1.9 MEUR (approx. 18 MSEK).
- An extraordinary annual general meeting is held in Oncology Venture on 17 January. A communiqué from the extraordinary annual general meeting is available at the Company's and AktieTorget's ([www.aktietorget.se](http://www.aktietorget.se)) respective websites.
- The Company advises on 9 January that CE labelling for Drug Response Predictor – DRP® – has undergone a technical validation and has been registered for Oncology Venture's leading drug candidate LiPlaCis®. A CE IVD validation (In-vitro diagnostics) and registration allows the product to be marketed within the EU and enables commercialisation in 32 European countries.

- Marie Foegh, MD, Dr.Sc., is offered on 3 January and accepts the position of CEO for 2X Oncology Inc. ("2X Oncology").

#### **Important events after expiry of the period**

- On 5 February 2018 Oncology Venture appoints Claus Frisenberg Pedersen as new Chief Financial Officer (CFO). Claus Frisenberg Pedersen succeeds Nikolaj Buhl Jensen, who is moving on to a position as Senior Consultant in the management company Buhl Oncology (Buhl Krone Holding APS).
  - Oncology Venture advises on 31 January 2018 the results of the other interim assessment of the phase-2 part of an ongoing phase 1/2 trial of LiPlaCis® - a targeted liposomal formulation of cisplatin - in difficult-to-treat patients with metastatic breast cancer. Clinical benefit has now been demonstrated in seven out of ten assessable patients who have been treated with LiPlaCis®, while conventional treatment with cisplatin in trials carried out previously resulted in a clinical response of only ten per cent in this patient category.
  - On 31 January, Oncology Venture advises that the Company's representative subscription of approx. MSEK 44.7 to finance planned clinical trials with existing drugs candidates and build up a financial buffer has been over-subscribed. The representative subscription was for approx. MSEK 59.6, equivalent to a subscription level of around 133 per cent. Through the representative subscription, 2,745,143 shares were newly issued and Oncology Venture made approx. MSEK 44.7 before subscription costs.
  - On 15 January 2018, Oncology Venture publishes the initial conclusions from a DRP® trial relating to a phase 3 TKI product from Big Pharma. In the study of biopsy data from renal cancer - where the DRP® results were compared with the results from clinical trials - a consistent result could be seen. On this basis, the Company's objective is now to further develop the drug and its DRP® commercially.
  - The subscription period for Oncology Venture's new share issue was initiated on 11 January 2018.
  - On 8 January 2018, Oncology Venture advises that the Company's CFO Nikolaj Buhl Jensen has used 100,000 options of the 2015/2018 series, which means that 107,000 new shares are issued at a rate of 6.88 SEK per share.
- On 4 January 2018, Oncology Venture publishes a prospectus on the occasion of the company's representative subscription which was initiated on 11 January 2018.
- An extraordinary annual general meeting is held in Oncology Venture on 4 January 2018. A communiqué from the extraordinary annual general meeting is available at the Company's and AktieTorget's ([www.aktietorget.se](http://www.aktietorget.se)) respective websites.

Below, you will find the pipeline of Oncology Venture. The company's aim is performing focused phase 2 studies and when positive results can be presented, to out-license, to further co-develop with a partner, or to sell the products.

Drug Candidate	Indication	Activity	Activity Initiated	Ownership
TKI	Kidney Cancer	DRP analysis of biopsies from phase 3 Tyrosinkinase inhibitor from Novartis	the initial conclusion from a study of the DRP of a phase 3 TKI product from Big Pharma showed a consistent result. Several parameters were evaluated in this blinded study and though some were not statistically significant, others were, and a consistent signal was seen of the TKI DRP's ability to foresee clinical benefit in the phase 3 TKI trial in renal cancer patients.	The TKI is planned to be developed by SPV company OV-SPV2 ApS, whereof 40 % is owned by Oncology Venture, 10 % by MPI and 50 % by external investors. It was recently announced Oncology Venture may acquire another 35 % of the OV-SPV2 shares before June 1, 2018. Oncology Venture announced in January 2018 that the board have decided to execute the license for the TKI product.
		Planning material for meeting with FDA	Ongoing	
<u>Oral PARP inhibitor – 2X-121</u>	Metastatic Breast Cancer	EISAI Phase 2 PARP inhibitor (E7449)	In-licensed. The company is now planning a defined phase 2 study, aimed to be financed with liquid assets from a planned rights issue. The study is expected to begin during 2018, and to be finished approximately 12 months later. After this, the company will be able to communicate the future of 2X-121.	2X-121 is developed by SPV company 2X Oncology Inc., whereof 92 % is owned by Oncology Venture and 8 % by external investors until a possible capital raise.
	Ovarian Cancer	Planning material for meeting with FDA	Ongoing	
<u>LiPlaCis®</u>	Breast Cancer	Screening patients (> 1300 patients)	Ongoing	Oncology Venture has signed an exclusive global license agreement with Liplasome Pharma, and possible future sales revenue will be divided as follows: Oncology Venture 45%, MPI 10% and Liplasome Pharma 45%. The company has also signed a development agreement with Cadila Pharmaceutical Ltd. Provided Cadila delivers according to this agreement, Oncology Venture's part of any future LiPlaCis® income will be 29,25 %.
		Phase 2 study*	Started Q3 2016. Inclusion of first 12 patients in the phase 2 part finished Q3 2017. New permit for up to 20 patients: ongoing. Last patient is expected to be included Q1 2018 and results are estimated to Q3-Q4 2018, depending on required length of patient treatment. Interim results announced in January 2018	
		Planning material for meeting with FDA	Ongoing	
	Breast Cancer	Randomized phase 2 study	To be initiated 2018. Inclusion of first patient Q2 2018, and last patient during Q4 2019. The study, estimated to include about 80 patients, has received EUROSARS funding in co-operation with our partner Smerud.	
	Skin, Head & Neck, Esophagus and Prostate Cancer, Cadila sponsored	Phase 2 studies	To be initiated by Cadila. The Indian authorities are very keen on its population not being used for pharmaceutical studies and has even stricter rules regarding for example stability studies than the rules in Europe and the US, which is the reason that the study takes longer time.	
	Breast Cancer, Cadila sponsored	Pivotal/phase 3 study	To be initiated by Cadila	
<u>TOP2 inhibitor – 2X-111</u>	Glioblastoma Metastatic Breast Cancer	Liposomal doxorubicin-Glutathione phase 2	In-licensed to 2X Oncology Inc. The company is planning a defined phase 2 study, intended to be financed with liquid assets from a planned rights issue. The study is estimated to begin during 2018, and to be finished approximately 12 months later. By then, the company will be able to communicate the future of 2X-111.	2X-111 is developed by SPV company 2X Oncology Inc., whereof 92 % is owned by Oncology Venture and 8 % by external investors until a possible capital raise.
<u>Irofulven</u>	Metastatic Prostate Cancer	Screening patients	Ongoing	Oncology Venture has acquired 75% of the rights to Irofulven from Lantern Pharma Inc. Lantern will receive 25 % of possible milestone payments, a number that may increase to 40% if Lantern makes use of their purchase option of 2 million USD when eight patients have been treated in the planned phase 2 study. Should Lantern use their option, Oncology Venture will own 60% and Lantern 40% of the rights for Irofulven.
		Study is approved by the Danish authorities. Preparing for initiation of phase 2 at Danish sites	Ongoing	
		Phase 2 study*	15 patients in phase 2 study. Last patient expected to be included during Q1 2019.	
<u>AP0010</u>	Immuno-oncology drug First Indication Multiple Myeloma (Bone Marrow Cancer)	Screening patients (approx. 150 patients)	Ongoing	Oncology Venture has acquired the rights for AP0010 from Onxeo. At a possible market launch, Oncology Venture will receive >90 % of the sales profit.
		Clinical phase 1/2 study	Phase 1 dose escalation part ongoing. Total phase 1 and 2 circa 30 patients, depending on how many patients are to be included in the phase 1 dose escalation part. If about 30 patients are included, the last patient is estimated to be included during Q1 2019.	
<u>Oral TOP1 inhibitor – 2X-131</u>		Oral TOP1 inhibitor phase 2 for development in patients suffering from Ovarian Cancer	Term Sheet under negotiation.	2X Oncology Inc.'s rights for 2X-131 are currently being negotiated.
Regarding Special Purpose Vehicles (SPV)		Seed investment of 3,5 million USD Series A financing	Secured in December 2016  Ongoing	

## Peter Buhl Jensen comments

Oncology Venture has made significant progress during 2017, which means we have been able to achieve the targets which were communicated before the start of the new year. We have entered into an agreement with the Big Pharma company on two drug candidates, and supplied early data from the ongoing phase 1/2 trial of LiPlaCis®. This result shows a good treatment effect in the selected patients, and confirms that our Drug Response Prediction (DRP®) technology works. We hope to be able to develop ourselves into a “preferred partner” for major pharmaceuticals companies as DRP® shows clinical evidence of being able to identify those patients that have the greatest chance of responding to the drug. We have already received a number of offers from the Big Pharma company for collaboration on various drug candidates, which shows that our activity is being followed with great interest.



In July 2017, we agreed on an option to in-license a phase 3 product from Novartis Pharma AG, one of the most successful developers of cancer drugs in the world. The agreement concerns a very promising small-molecular kinase inhibitor (TKI) in clinical phase 3 development, and is divided into two parts. Negotiations on both parts are completed and Oncology Venture will decide whether the final part will be signed. The first part of the agreement gives permission to check beforehand whether DRP® is able to identify which patients benefit from the treatment with TKI in a phase 3 trial of renal cancer. Biopsy data from 150 patients have been analysed with our DRP® technology and in January 2018 we were able to report a consistent result for the TKI inhibitor. The TKI product will be the strongest and most advanced in Oncology Venture’s pipeline, with a clear effect in several cancer types. I am convinced that we can develop the TKI project for commercialisation, and when we have the full data package we can continue to develop DRP® to a tool that can be used for clinical guidance to predict the drug’s benefit for patients.

The other Big Pharma agreement was also concluded in July, when we signed an exclusive global licensing agreement with Eisai Inc. on the phase 2 PARP inhibitor E7449, which we now call 2X-121. The ground-breaking science and convincing clinical results behind 2X-121, combined with DRP®, just as with the TKI product I mentioned above, provides an exceptional reduced-risks opportunity to develop effective treatments for cancer types that are difficult to treat. We were already able to announce in August that DRP® has been able to identify respondents and non-respondents for 2X-121 successfully and with statistical significance among the 13 patients examined in a phase 1 trial which had been previously carried out by Eisai. The results, based on patient biopsies, are as good as we could have hoped for. With the help of DRP®, we have taken a major step towards the PARP market.

The above-mentioned progress has been made in our two SPV companies 2X Oncology and OV-SPV2, but also Oncology Venture’s own pipeline has taken clear steps forward. In January 2018 we reported the results of the second interim assessment from the phase 2 part of an ongoing phase 1/2 trial of LiPlaCis®. Clinical benefit has now been demonstrated in seven out of ten assessable patients who have been treated with LiPlaCis®, while conventional treatment with cisplatin in trials carried out previously resulted in a clinical response of only ten per cent in this patient category. We are very happy to announce that the interim results from the phase 2 part of the trial meet our very high expectations. The effect that has been observed in patients with difficult-to-treat metastatic breast cancer, who had on average undergone previous cancer therapy on seven occasions, is remarkable. We expect to be able to present the final results during the second half of 2018, the exact time depends mainly on how long the patients will be treated. My expectations of the combination of LiPlaCis® and DRP® are high, as the focused treatment has the potential to bring new hope and better treatment for cancer patients.

The development of 2X-111, Irofulven and APO010 is also going according to plan. Our overall objective is to carry out focused phase 2 trials of DRP®, which are expected to take around 12 months. If the outcome of the trials is positive, our objective will be to either out-license and further develop the drug with a partner or to sell the products. Our pipeline has experienced a very positive development during the second half of 2017 and we are currently preparing for several meetings, including the “End of Phase 2” meetings with FDA in the USA, provided that TKI DRP® shows good prognostic capacity. The new share issue of approx. MSEK 44.7 that has recently been implemented is financing our activity throughout 2018, and gives us the opportunity to carry out the planned clinical trials and also provides us with a satisfactory financial buffer. Based on the past year’s successes of Oncology Venture’s attractive drug project, we will continue to break new ground in the development of cancer drugs during 2018.

**Peter Buhl Jensen – CEO, Oncology Venture Sweden AB**

### About Oncology Venture

Many anti-cancer drugs are only beneficial to a minor part of a patient group, and there is currently no way of identifying which patient will respond to a certain treatment. This is forcing oncologists to treat many patients blindly, and if the number of patients responding to a certain drug is too low, the drug candidate will most likely not be used even if it may in fact be well suited for some patients. The same problem occurs in medical studies of drug candidates. Insufficient efficacy has become the most common reason for clinical failures within drug development. A great part of these failures cannot be attributed to the drug as such, but are instead a consequence of difficulties performing clinical studies in an adequate way, i.e. with a satisfactory well-defined patient group.

The operating subsidiary Oncology Venture ApS holds a license from Medical Prognosis Institute A/S (MPI) to use the technology Drug Response Predictor (DRP®). Since June 2016, MPI is listed at Nasdaq First North, Stockholm.

DRP® enables identification of which patients will respond to a certain drug candidate, thus increasing the likeliness for a drug candidate to succeed in clinical studies.

### Business Model in Short

Oncology Venture's business is built on optimizing the use of anti-cancer drugs that have shown efficacy but stalled in clinical development, either due to insufficient response rate, or due to difficulties in raising enough capital to drive the business forward. The company works with a model that better the odds compared to traditional drug development. Instead of treating all patients suffering from a specific type of cancer, the patients are first screened, and only those likely to respond to treatment with the specific drug will then be treated. With a more well-defined patient group, the use of the drug is optimized, and risks and costs are reduced. At the same time, both treatment and development become more efficient.

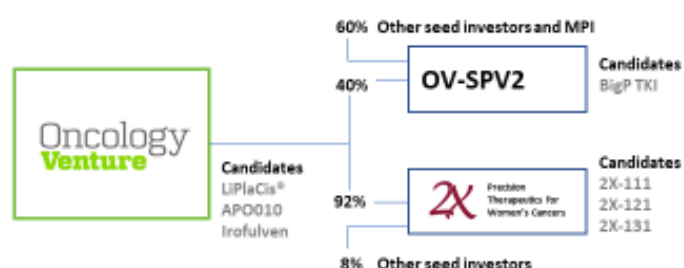
Oncology Venture shall in-licence (or buy) drug candidates that have been stopped in clinical development, and thereafter perform new clinical studies based on extended knowledge of which patients are likely to respond to a specific drug candidate. OV has recently reached a new level by being able to in-licence high quality Big Pharma products referring to the company's success criteria: efficacy, favourable side effect profile, positive manufacturing process - preferably existing products – all regulatory documents in place, and good business potential. Oncology Venture's ambition is to in-licence effective drug candidates where the company's DRP technology can be used for reaching success as far as high precision, and to perform focused phase 2 studies on a well-defined population based on relevant bio markers.

It is also part of Oncology Venture's business model to create SPVs, i.e. privately owned spin-out companies, thereby becoming the owner of several projects and exporting technology to other countries. This way, more capital can be raised from different types of investors including venture capital, business angels and private family businesses around the world without intention to invest in listed companies (more scoring opportunities in attracting capital). 4 million USD has already been raised for 2X Oncology and OV-SPV2. Oncology Venture in-licenses the products which are placed in the SPV's if these can raise sufficient funding to run the clinical development. After performed clinical studies, Oncology Venture will out-licence (or sell) drug candidates with a high response rate connected to a DRP test. A deal in this phase typically includes incomes at the time of out-licensing (up-front), plus milestone and royalty incomes. Oncology Venture has also been able to attract public financing for several projects, and intend to remain proactive within this field.

### Company Structure and Shareholding

Oncology Venture Sweden AB owns 100 % of the subsidiary Oncology Venture ApS. All operations take place within the subsidiary, and the only operative procedure of Oncology Venture Sweden AB is owning the subsidiary Oncology Venture ApS. Beyond this, Oncology Venture ApS owns 92 % of American subsidiary 2X Oncology, and 40 % of spin-out company OV-SPV2 ApS with an

option until June 1, 2018 to increase ownership to 75% for 3,5 million USD. Further on, the SPVs will be owned by Oncology Venture ApS together with new investors - a split between the parts will be negotiated and determined.





## Oncology Venture's Drug Candidates

### APO010

Oncology Venture holds the exclusive global rights for drug candidate APO010, which is currently in its phase 1 dose escalation part of clinical phase 1/2 development. In March 2017, the Danish Medicines Agency approved Oncology Venture's focused study of APO010 in Multiple Myeloma, meaning a previously manufactured stock of APO010 could be used in the study. APO010 is a FAS-receptor immuno-oncology product that kills cancer cells through the same mechanism as the T cells of the human body. Four Danish haematology clinics are open in the study, recruiting patients. So far, over 70 patients have approved to have their tumors DRP scanned for sensitivity to APO010. The study began with the first patient being included in May, 2017.

The company holds all rights for this candidate, rights transferred from TopoTarget A/S (later Onxeo) during 2012.

The APO010 project has received a EUROSTARS grant of 13.5 million SEK. Oncology Venture has acquired the DRP® for APO010 from MPI, meaning OV holds all rights to the APO010-DRP in the foreseeable future.

### Seven drugs in OV's pipeline with strong newsflow in 2018

- Orange is ongoing clinical trials – full Green is ongoing screening studies –

dotted green are to commence in 2018



### Irofulven

Irofulven has previously undergone phase 2 and 3 studies and shown a 10% response rate (RR) in patients suffering from Prostate Cancer, 13% RR in Ovarian Cancer patients, and 7% RR in Liver Cancer. However, these levels are insufficient for obtaining authority approval. With the help of Professor Knudsen's DRP® for the product, the company aims to find patients who are likely to respond to Irofulven treatment, and include these patients in a focused phase 2 study to increase the response rate. After Q2 2017, it was announced that Irofulven had successfully been manufactured and bottled in injection bottles for clinical studies. Oncology Venture submitted the clinical trial application to the authorities in October for initiating the studies in Denmark and Sweden, where the company has screened >70 Prostate Cancer patients. Oncology Venture is negotiating with potential partners in China for development of Irofulven in Liver Cancer.

### LiPlaCis

LiPlaCis® is a liposomal formulation of the active substance cisplatin, first and foremost aiming to treat Breast Cancer patients. In the phase 1/2 study of LiPlaCis®, a phase 1 dose escalation phase among patients with advanced tumors has been performed. The phase 1 part is finished, and the first goal of including 12-15 patients in the phase 2 part was reached during the third quarter of 2017. Furthermore, the number of patients was increased to up to 20 for further investigation of the cut-off of the DRP®. The company has been allowed to increase the cut-off of 20% with highest DRP score to include 2/3 of the patients with highest DRP score which increases the possibility to identify the relevant cut-off level and to expand the study from 12 to up to 20 patients. After this, the company plans to initiate an international, randomised phase 2 multicentre study in Europe. Preparations for this are ongoing. The first DRP positive Breast Cancer patient has shown partial remission (i.e. > 30% reduction of the tumor) after treatment with LiPlaCis®. Data from the ongoing phase 1/2 study show how the tumor response to LiPlaCis® can be predicted with Oncology Venture's Drug Response Predictor (DRP®) regardless of tumor type, including Breast Cancer. In January 2018, Oncology Venture announced the results of the second interim evaluation from the Phase 2 part of an ongoing Phase 1/2-study of LiPlaCis – a targeted liposomal formulation of cisplatin – in difficult-to-treat patients with metastatic breast cancer. Clinical effect has now been shown in 7 out of 10 evaluable patients treated with LiPlaCis®, while conventional treatment with cisplatin in earlier conducted studies has resulted in a clinical response of only ten percent in this patient category. Beyond this, the Danish Medicines Agency and The Ethics Committee gave their permission to include Metastatic Breast Cancer patients in the phase 2 study of LiPlaCis® already after the patient's second line of treatment. The possibility of partaking in the phase 2 study of LiPlaCis can now be offered to the patients earlier in their treatment process. This gives more patients a potential new treatment, and enables an expansion of the LiPlaCis

indication. The LiPlaCis® programme has achieved a higher value through a permission for treating patients with symptoms from liver metastases and patients with low thrombocyte count - patients excluded from many other drug treatments.

Oncology Venture has signed a development agreement with Cadila Pharmaceuticals Ltd regarding joint development of LiPlaCis® in combination with its DRP®. According to the agreement, Cadila Pharmaceuticals has the possibility to acquire a 35 % ownership of the drug's value, given they can prove clinical data of FDA/EMA quality from 320 patients within a certain time frame. The aim is to evaluate the effect of LiPlaCis® in several different indications in focused phase 2 studies, and to perform a randomized phase 3 study as a base for and important part of the data package for market approval by the FDA, EMA and CDSCO (Central Drugs Standard Control Organisation of India). Cadila will be using chilled product and stability studies for this product version. The Indian authorities are very particular their population must not be used as "guinea pigs of the world", and have even stricter rules for stability studies than those of Europe and the US. This is the reason why the study takes longer. The phase 2 studies are expected to begin within Head and Neck, Prostate, Skin and Esophagus Cancer. The company is also looking forward to the start of the Cadila phase 3 study in Metastatic Breast Cancer. Cadila Pharmaceuticals Ltd. will invest in the form of research and development activities regarding 320 cancer patients, and DRP screening of over 1400 patients. Oncology Venture has acquired the DRP for LiPlaCis® from MPI, meaning OV holds all future rights for LiPlaCis®-DRP™ for the foreseeable future.

## Special Purpose Vehicles

### 2X Oncology

#### 2X-111

Previously called 2B3-101, 2X-111 is a liposomal formulation of doxorubin, using so called G technology to enable the drug of passing the blood-brain barrier to better the treatment of brain metastases and primary brain tumors. 2X-111 has shown clinical activity in a phase 2 study with patients suffering from Metastatic Breast Cancer, and in patients with Glioblastoma (primary Brain Cancer). These are both hard-to-treat cancers with great medical needs. 2X-111 will be combined with its Drug Response Predictor (DRP®) as companion diagnostics in DRP focused phase 2 studies for patients with high likelihood of responding to the treatment.

### 2X Oncology Inc. and OV-SPV2 ApS

Orange is ongoing clinical trials – full Green is ongoing screening studies – dotted green are to commence



#### 2X-121

Oncology Venture has signed an agreement with Big Pharma company Eisai to develop companion diagnostics for an oncology therapeutic drug candidate from this company, a so called PARP inhibitor. The aim was to evaluate Oncology Venture's interest in in-licensing the drug for further clinical development within 2X Oncology, which also did happen after the end of Q2 2017. After Q2 2017, Oncology Venture could also announce having identified the responding patients. In a blinded study, Professor Knudsen's DRP® analysis showed how DRP from 13 patients could accurately predict response and overall survival with a p value of 0.07, meaning there is a 7% risk of the result being a random outcome. The company has pills in stock for the projects, facilitating for a quick start.

Also in this case, DRP® has been evaluated as a potential game changer for Big Pharma company Eisai's high quality PARP inhibitor. Should Oncology Venture's DRP® achieve positive results, the combination of the drug and its companion diagnostics has great market potential.

#### 2X-131

Oncology Venture is currently negotiating a possible inclusion of a TOP1 inhibitor, hereby referred to as 2X-131, to be developed for patients suffering from Ovarian Cancer. The plan is to test the drug candidate in a focused phase 2 study in combination with the Company's DRP®, with the aim of improving the response rate.

#### OV-SPV2

During 2017, Oncology Venture has formed an additional oncology therapeutic spin-out OV-SPV2 for the development of a specific drug against cancer, utilizing DRP®. OV-SPV2 intends to test and potentially develop an oral tyrosine kinase inhibitor from Novartis Pharma AG, currently holding the worldwide rights to this anticancer drug. Analysis setup from previous phase 3 studies of the TKI product is ongoing. The company is currently working together with FDA and EMA regulatory experts in evaluating the possibility to discuss a potential fast approval from the regulatory authorities. The drug has previously shown very competitive and interesting data in both Liver and Kidney Cancer. The drug candidate has been tested in phase 2 and phase 3 studies, and biopsies and results are available from these trials.

Oncology Venture has conducted a fast DRP® test to assess whether the DRP® tool can identify respondents from the clinical trials. In the study of biopsy data from renal cancer patients – where DRP® results were compared with results from clinical studies – a consistent result was identified. Based on this, the Company's goal is to continue the drug and its DRP® to commercial success. Several parameters were evaluated in this blinded study and though some were not statistically significant, others were, and a consistent signal was identified regarding the TKI DRP's ability to predict clinical benefit in the Phase 3 TKI study of renal cancer patients. Oncology Venture has decided to execute the license option for the TKI, the conditions of which have been previously negotiated.

## Development in Numbers during the Fourth Quarter of 2017

### Revenue

Net revenue for the fourth quarter amounted to 0 (1 169) KSEK.

### Result

The company's result after taxes for the fourth quarter amounted to -22 527 (-18 618) KSEK, and was mainly influenced by operating costs, amounting to -26 314 KSEK. These mainly consisted of one-off production costs of approximately 7 000 KSEK (mainly regarding manufacturing of Irofulven), 4 000 KSEK regarding screening and clinical site costs and 3 300 KSEK regarding costs for clinical research operations, mainly regarding preparation of Phase 2 studies. 5 400 KSEK are referred to costs borne by 2X Oncology, whose accounts are incorporated into Oncology Venture's group accounts.

### Cash and Bank

Per December 31, 2017, the cash and bank of Oncology Venture 11 977 (18 872) KSEK. Besides this, Oncology Venture holds short-term receivables of 6 667 (13 595) KSEK, consisting of receivables and other prepaid costs.

After the end of the quarter, Oncology Venture has conducted a rights issue which provided the Company with SEK 44,7 million before issuance costs.

### **The Share**

The shares of Oncology Venture Sweden AB were listed on AktieTorget on July 22, 2015. The short name/ticker is OV, and the ISIN code is SE0007157409. AktieTorget is a secondary name of ATS Finans AB, which is a securities company under supervision of the Swedish Financial Supervisory Authority (Finansinspektionen). AktieTorget runs a trading platform (MTF), which is a non-regulated market. Per September 30, 2017, the number of shares was 10 980 573. Each share equals the same rights to the company's assets and result.

### **List of Share Holders Owning Over 5% per 2017-11-30**

<b>Name</b>	<b>Share of Votes And Capital (%)</b>
Sass & Larsen ApS	14,53
Buhl Krone Holding ApS*	11,47
Medical Prognosis Institute A/S**	10,64
Other shareholders	63,36
<b>Total</b>	<b>100,00</b>

\* 80 % owned by Peter Buhl Jensen (CEO of Oncology Venture Sweden AB). The other 20 % owned by Ulla Hald Buhl, board member of Oncology Venture Sweden AB, and married to Peter Buhl Jensen.

\*\* 10,49 % owned by Peter Buhl Jensen (CEO of Oncology Venture Sweden AB) and spouse.

### **Warrants**

At an Extraordinary General Meeting on June 28, 2015, a decision was made to introduce three stock option programs for The Company's employees and board members. The option programs contain a total of 325 000 warrants.

#### Warrant Program 1

This program consists of 170 000 warrants, and is directed to key employees who worked with the Initial Public Offering of Oncology Venture Sweden AB. The warrants were received free of charge, and can be subscribed to during a period that expires on August 22, 2018. Each warrant entitles subscription to 1.07 new share in Oncology Venture Sweden AB at a rate of 6.88 SEK per share. The warrants have a lock-up period of one year, which is transferred to stock shares if the warrants are used during the first year.

#### Warrant Program 2

Consists of 125 000 warrants received free of charge, and is directed to employees of the company, among these board member Ulla Hald Buhl, Nils Brünner, and board member Steen Knudsen, who all received 10 000 warrants each. One third of the warrants can be subscribed to at a rate of 7.58 SEK per share between August 1, 2016 and August 22, 2018. Another

third can be subscribed to at a rate of 8.34 SEK per share between August 1, 2017 and August 22, 2018. The remaining third of the warrants can be subscribed to at a rate of 9.16 SEK per share during August 1 to August 22, 2018. Each warrant entitles subscription to 1.07 new share in the company. Should a warrant holder leave his or her employment before the end of the first subscription period, all warrants will return to the company. If an employee leaves after the end of the first subscription period, two thirds of his/her warrants will return to the company. If leaving after the second subscription period, one third of the employee's warrants will return to the company.

#### Warrant Program 3

Consists of 30 000 warrants and is directed to Duncan Moore and Sanjeevi Carani, board members of Oncology Venture. Each warrant entitles subscription to 1.07 new share in Oncology Venture Sweden AB at a rate of 13.96 SEK per share. The warrants can be subscribed to August 1-22, 2018. Moore and Carani are offered warrants at a price of 1.15 SEK per warrant.

#### Warrants as consideration for exclusive license from MPI

As consideration for the extended exclusive license, MPI has received a total of 302 243 warrants, entitling the signing of stock shares in Oncology Venture Sweden AB. The warrants entitle signing of one share per warrant at a subscription price of 10 SEK per share. The warrants can be exercised until December 31, 2019. At full exercise of the warrants, the total dilution will be approximately 2.8 % (based on the 10 877 007 shares currently outstanding in Oncology Venture, but excluding those shares that would be added when/if current outstanding warrants in Oncology Venture Sweden AB are exercised). Per the date of this document, MPI has exercised 100 000 of above mentioned warrants. Through exercising the warrants, approximately 1 000 000 SEK was added to the Company. After this exercise, MPI holds 202 243 warrants.

#### **Risks and Uncertainties Related to Company Operations**

In short, the risks and uncertainties applicable to Oncology Venture's company operations relate to drug development, competition, technology development, patents, authority requirements, capital needs, currencies and interest rates. During the current period, no major changes in risks or uncertainty factors have occurred. For a more detailed presentation of risks and uncertainties, we kindly refer you to a previous Prospectus published in March 2017.

#### **Auditor's Review**

In accordance with AktieTorget's regulations, the report has not been reviewed by The Company's auditor.

#### **Principles for Interim Report**

The interim report has been made in accordance with Swedish jurisdiction for annual accounts, and following general advice of the Swedish National Board of Accounting 2012:01, Annual Accounts and Consolidated Accounts ("K3" and in accordance with "BFNAR 2007:1 Voluntary Interim Reporting"). For further information on accounting principles, we refer to the Annual Accounts of Oncology Venture for 2016.

#### **Financial Calendar**

Q1 Report 2018	31 May 2018
General Annual Meeting 2018	17 May 2018
Q2 Report 2018	31 August 2018
Q3 Report 2018	30 November 2018
Q4 Report 2018	28 February 2018

*The Board and CEO hereby certify that the interim report gives an accurate overview of The Company's operations.*

Hoersholm, February 28, 2018  
Oncology Venture Sweden AB  
*The Board and CEO*

**For further information regarding Oncology Venture, kindly contact:**

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## Financial Overview

### Summary of Profit and Loss Account - Business Group

(KSEK)	01-10-2017 31-12-2017	01-01-2017 31-12-2017	01-10-2016 31-12-2016	01-01-2016 31-12-2016
Revenue	0	2.091	596	1.305
Operating costs	-26.409	-62.999	-20.934	-39.645
Depreciation and impairment losses on tangible and intangible assets	-185	-6.554	-800	-2.534
Sum of operating costs	-26.594	-69.553	-21.734	-42.179
Operating profit	-26.594	-67.462	-21.138	-40.874
Financial items	2.759	3.801	307	346
Profit before tax	-23.835	-63.661	-20.831	-40.528
Tax	1.308	7.114	2.213	6.985
Profit for the period	-22.527	-56.547	-18.618	-33.543
Basic and diluted earnings per share, based on average number of shares	SEK -2,07	SEK -5,20	SEK -1,85	SEK -1,95

### Summary of Balance Sheet - Business Group

(KSEK)	31-12-2017	31-12-2016
Balance		
Intangible assets (note 1)		
Goodwill	20.516	20.516
Depreciations, goodwill	-5.129	-3.078
Rights and patents	29.246	1.447
Tangible fixed assets	485	624
Financial fixed assets	266	258
Inventory	9.149	316
Tax receivable	7.270	6.985
Receivables	6.647	13.595
Cash and bank	11.978	18.872
Assets	80.426	59.535
Share capital	1.523	1.410
Share premium	133.100	85.144
Issuance of warrant in connection with acquisition of intangible right	12.165	0
Retained earnings	-62.077	-5.648
Period earnings	-22.527	-33.543
Non-controlling interests	3.866	0
Equity	66.050	47.363
Other liabilities	14.376	12.172
Current liabilities	14.376	12.172
Total equity, provisions and liabilities	80.426	59.535

### Summary of Change in Equity - Business Group

	01-10-2017	01-01-2017	01-10-2016	01-01-2016
(KSEK)	31-12-2017	31-12-2017	31-12-2016	31-12-2016
Shareholders equity at beginning of period	85.933	47.363	35.214	41.634
Translation difference (OV APS, 2XO OV-SPV)	863	-656	0	0
Issuance of warrant in connection with acquisition of intangible right	-	12.165	0	0
Korrigerer till början	-	0	-	0
Capital increase	-	64.231	20.898	41.565
Emission costs	-	-3.806	-646	-2.293
Adjustment goodwill	-513	-513	0	0
Change in Non-controlling interests	2.346	3.866	0	0
Net income	-22.527	-56.546	-8.103	-33.543
Shareholder's equity at end of period	<b>66.103</b>	<b>66.103</b>	<b>47.363</b>	<b>47.363</b>

### Summary of Cashflow – Business Group

	01-10-2017	01-01-2017	01-10-2016	01-01-2016
(KSEK)	31-12-2017	31-12-2017	31-12-2016	31-12-2016
Profit before tax	-26.594	-67.461	-20.830	-33.543
Depreciation	185	6.554	799	2.534
Working capital	17.693	6.027	5.236	-31.009
Translation difference working capital	-577	-826	-	-5.057
Cash-flow from operating activities	-9.293	-55.706	-14.795	-36.066
Interest income	2.759	3.985	291	346
Interest paid	-	-184	-	-
Paid or adjusted taxes	4.400	4.400	0	0
Cash-flow from operations	<b>-2.134</b>	<b>-47.505</b>	<b>-14.504</b>	<b>-35.720</b>
Investment in intangible fixed assets	-5.079	-31.878	-	-2.296
Investment in tangible fixed assets	16	229	1.067	624
Investment in financial fixed assets	-5	-5	0	258
Translation difference fixed assets	105	-354	-	-
Acquisition of subsidiary	-	0	0	0
Cash-flow from investment activities	<b>-4.962</b>	<b>-32.008</b>	<b>1.067</b>	<b>-1.414</b>
Loans	-	0	0	0
Capital increase	-	61.626	20.503	39.523
Issuance of warrant in connection with acquisition of intangible right	-	12.165	-	-
Cash-flow from financial activities	-	<b>73.791</b>	<b>20.503</b>	<b>39.523</b>
Total cash-flow for period	<b>-7.096</b>	<b>-5.722</b>	<b>7.066</b>	<b>2.389</b>
Cash at start of period	19.053	18.872	11.782	16.786
Translation difference (OV APS)	20	-1.174	24	-303
Cash at end of period	<b>11.977</b>	<b>11.977</b>	<b>18.872</b>	<b>18.872</b>

#### Note 1:

Issue for non-cash consideration in conjunction with establishing the Swedish AB (30.904 KSEK) was made at the expected IPO rate (7,40 SEK). It is the management's assessment that this value reflects the market value of the company's intangible assets. In May 2016, the company made a rights issue of 2 066 624 stock shares at the expected issue price of 10 SEK/share. In October 2016, the company undertook a rights issue of 774 984 stock shares at the expected issue price of 29 SEK/share. It is the management's assessment that the above values reflect the market value of the company's intangible assets. During March 2017, the company undertook a rights issue of 802 213 stock shares at the issue price of 42 SEK/share. Non-tangible assets are classified as goodwill, and are depreciated over a period of ten years.



### Summary of Profit And Loss Account - Parent Company

	01-10-2017	01-01-2017	01-10-2016	01-01-2016
(KSEK)	31-12-2017	31-12-2017	31-12-2016	31-12-2016
Revenue	-	0	0	0
Operating costs	-551	-2.486	-2.128	-2.455
Depreciation and impairment losses on tangible and intangible assets	2.703	-	-	-
Operating profit	2.153	-2.486	-2.128	-2.455
Financial items	748	572	178	316
Profit before tax	2.901	-1.914	-1.950	-2.139
Tax	-	-	-	-
Profit for the period	2.901	-1.914	-1.950	-2.139

### Summary of Balance Sheet - -- Parent Company

(KSEK)	31-12-2017	31-12-2016
Balance		
Intangible assets	-	-
Financial fixed assets	28.644	28.644
Receivables	138	57
Receivables from business group	98.063	56.984
Assets	126.845	85.685
Share capital	1.523	1.410
Premium fund	117.156	85.322
Issuance of warrant in connection with acquisition of intangible right	12.165	-
Retained earnings	-7.052	-98
Period earnings	2.901	-2.139
Equity	126.693	84.495
Accrued expenses and prepaid income	152	1.190
Short-term receivables	152	1.190
Total equity, provisions and liabilities	126.845	85.685

### Summary of Change in Equity – Parent Company

	01-10-2017	01-01-2017	01-10-2016	01-01-2016
(KSEK)	31-12-2017	31-12-2017	31-12-2016	31-12-2016
Shareholder's equity at beginning of period	123.792	84.495	65.942	47.112
Capital increase	-	34.693	20.503	39.522
Emission costs	-	-2.746	-	-
Issuance of warrant in connection with acquisition of intangible right	-	12.165	-	-
Net income	2.901	-1.914	-1.950	-2.139
Shareholder's equity at end of period	126.693	126.693	84.495	84.495

# Oncology **Venture**

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