orexo

Interim Report Q1 2019

Continued strong performance from the US business

Q1 2019 highlights

- Total net revenues of SEK 174.3 million (139.7), up 24.8 percent
- Zubsolv® US net revenues of SEK 161.7 million (131.1), up 23.3 percent in SEK and 9.3 percent in local currency
- EBITDA of SEK 12.0 million (-16.6), EBITDA excluding IP litigation costs of SEK 60.8 million (-8.5)
- US EBIT of SEK 71.9 million (25.3)
- Cash flow from operating activities of SEK 50.9 million (106.3), building a cash balance of SEK 647.4 million (437.5)
- Net earnings of SEK 14.1 million (-25.9)
- Positive results from human PK study assessing Orexo's new intranasal naloxone formulations (OX124) for opioid overdose reversal
- The US District Court of Delaware issued a final, non-appealable judgement that Actavis's generic Zubsolv products infringe the US patent ´330, preventing Actavis from launching their infringing generics in the US until 2032
- The US District Court of Delaware ruled that Actavis does not infringe in Orexo´s patent ´996 with their Suboxone® and Subutex® generics
- Updated full year outlook with accelerated COGS reduction, reaching 35 percent reduction on full year basis

144 %
US EBIT, growth in local currency

SEK 51 m
Cash flow from operating activities

SEK 647 m
Cash and cash equivalents

SEK m, unless otherwise stated	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec	12 mth Apr 2018-Mar 2019	12 mth Apr 2017-Mar 2018
Net revenues	174.3	139.7	783.1	817.7	656.0
whereof Zubsolv® US net revenue	161.7	131.1	621.5	652.1	502.8
Cost of goods sold	-25.3	-48.4	-171.8	-148.7	-166.6
Operating expenses	-147.9	-113.1	-515.6	-550.4	-430.6
EBIT	1.1	-21.8	95.8	118.7	58.8
EBIT margin, %	0.6	-15.6	12.2	14.5	9.0
US EBIT	71.9	25.3	198.3	244.8	98.6
US EBIT margin, %	44.5	19.3	31.9	37.5	19.6
EBITDA	12.0	-16.6	116.6	145.2	79.7
Earnings per share, before dilution, SEK	0.41	-0.75	3.99	5.15	0.92
Earnings per share, after dilution, SEK	0.40	-0.75	3.93	5.05	0.92
Cash flow from operating activities	50.9	106.3	242.0	186.9	224.4
Cash and cash equivalents	647.4	437.5	589.8	647.4	437.5

Unless otherwise stated in this report, all data refers to the Group, and numbers relate to the actual quarter while numbers in parentheses relate to the corresponding period in 2018.

Content

About Orexo
Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid dependence and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via selected partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2018 amounted to SEK 783.1 million and the number of employees was 129. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

For further information, please contact
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Presentation
At 2.00 pm CET, the same day as the announcement of the report, Orexo invites analysts, investors and media to attend an audiocast with a web presentation where Nikolaj Sørensen, CEO, and Joseph DeFeo, CFO, will present the report. After the presentation a Q&A will be held. Questions can also be sent in advance to ir@orexo.com, no later than 11.00 am CET. Please view the instructions below on how to participate.
Internet: https://tv.streamfabriken.com/orexo-q1-2019
Telephone: SE: +46 8 505 583 50 UK: +44 333 300 9274 US: +1 833 526 8381
The presentation material will be available on Orexo´s website prior to the audiocast.

Financial calendar
Interim Report Q2 2019 - July 11, 2019 at 8.00 am CET
Interim Report Q3 2019 - October 24 at 8:00 am CET
Full Year Report incl. Q4 2019 - January 30, 2020 at 8:00 am CET

For more information about Orexo
Please visit, www.orexo.com.You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

Demonstrating resilience and growth in a dynamic market

The first quarter of 2019 has been eventful from a market perspective, most notably with the entry of generic competition to Suboxone® Film. In this dynamic landscape I am pleased to see Zubsolv® maintaining strong sales growth and greater profit contribution, supporting further enhancement of our pipeline development.

Strong financial performance – US operations reach 44.5 percent EBIT margin (19.3)
I am pleased to report the business has achieved a profitable first quarter – the first for the company. This was achieved despite expected high legal costs during the period. Excluding the litigation costs, EBITDA reached SEK 60.8 million (SEK 12.0 million including). Profitability reflects the strong growth in Zubsolv sales in combination with improved gross margins due to accelerated reduction in cost of goods sold. The EBIT margin in our US operation has now reached 44.5 percent and contributed to our overall profitability with SEK 71.9 million.

Market dynamics – Zubsolv sales resilient to increased generic competition
During the quarter generic versions of Suboxone Film were launched. We are encouraged to see limited impact on Zubsolv sales, which have remained resilient and stayed at similar levels reported in Q418 and demand increased by 6 percent versus Q118. The main challenge is that some insurers, e.g. Humana and WellCare, who previously didn't cover Suboxone Film, will now reimburse the generic versions of the drug. Although increased competition can have negative impact on market share, the total profit contribution from these insurers often increase, since the rebates are substantially reduced. When the current turmoil has settled we are confident the market will offer opportunities for Zubsolv.

Operational – increasing the pace of pipeline developments
As previously announced, we received encouraging data on our OX124 project for the treatment of opioid overdose with a nasal naloxone formulation. We are now in a position to progress both OX124 and OX125 (nasal nalmefene formulation), into further clinical studies which will be initiated in 2020. We also received positive in-vivo data for OX338, a sublingual formulation with ketorolac for treatment of pain, and plan to initiate the first clinical study in humans later in 2019.

Legal – no impact on Zubsolv from the negative decision in the Actavis litigation
Orexo is an innovative company and our main product Zubsolv is patent protected until 2032 following a multiyear patent dispute with Actavis. Being an innovative company also requires a fierce protection of our innovations and we are disappointed with the recent outcome to the litigation process against Actavis for their generics of Subutex® and Suboxone® tablets. We will now initiate the first step in an appeal process. This will be associated with significantly lower costs than the legal expenses recorded in Q119.

Summary and outlook
We have had a strong start to 2019. Three of our four internal pipeline projects are ready to progress into the next development phase, our financial position continues to strengthen due to sales growth and our manufacturing efficiency program has had significant positive impact on the gross profit contribution from Zubsolv. With a continuous improving profit contribution from Zubsolv, we are able to invest more into R&D and business development. The success in these areas will define our future and on all these areas we have made good progress during the period.

Uppsala, Sweden, May 2, 2019

Nikolaj Sørensen

President and CEO

Financial information

Revenues

Total revenues amounted to SEK 174.3 million (139.7), corresponding to an 24.8 percent increase. The increase was driven by strong Zubsolv® US growth, reaching 23.3 percent in SEK.

Zubsolv US revenues amounted to SEK 161.7 million (131.1), corresponding to 23.3 percent growth in SEK. In local currency (USD) the equivalent growth rate was 9.3 percent, equal to sales of USD 17.6 million. The main growth driver in local currency was the 6 percent increase in demand (NTRx) driven by improved market access from January 1, 2019. Net price was positively impacted by the 4 percent price increase from January 1, 2019, and by a USD 0.5 million adjustment of rebates relating to prior periods. Wholesaler inventory levels were reduced by USD 0.5 million during the quarter development allowing optimization of inventory levels. The SEK/USD exchange rate had a positive impact.

Abstral® royalty amounted to SEK 10.9 million (5.8). The increase was primarily driven by true-up adjustments made to prior period estimates. Royalty for sales in Europe will be received until December 31, 2019, when the European contract with Kyowa Kirin expires.

Royalty from Edluar® amounted to SEK 1.7 million (2.8).

Costs of goods sold

Cost of goods sold (COGS) amounted to SEK 25.3 million (48.4) for the quarter all related to Zubsolv in the US market. This corresponds to an average COGS per tablet 43 percent lower than the average realized in 2017.

Orexo achieved its 2H 2019 cost reduction goal of 35 percent versus 2017 this quarter, ahead of schedule. We anticipate that ongoing cost reduction efforts will yield efficiencies at this level for the remainder of 2019. The reduction compared to 2018 will be approximately 30 percent.

Operating expenses

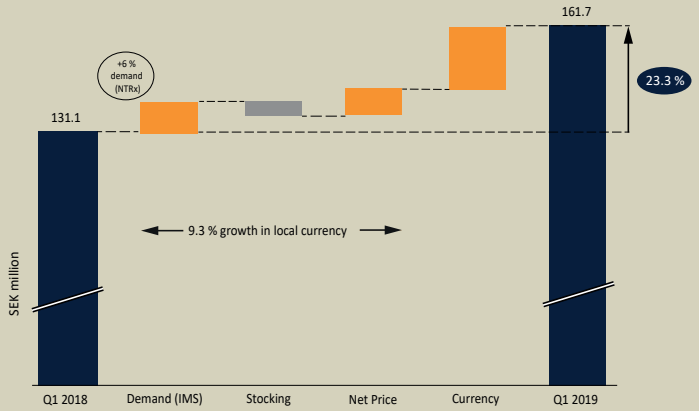
Selling expenses amounted to SEK 47.2 million (43.3). The increase over same period last year is explained by expanded sales force for the Ohio Medicaid access win and additional market research expenses together with stronger US currency.

Administrative expenses amounted to SEK 70.1 million (27.2). The significant increase versus prior year is explained by higher legal expenses related to the patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US, see Note 3. Legal expenses for IP litigations reached SEK 48.8 million (8.2) for the quarter.

Research and development costs amounted to SEK 37.6 million (45.3). The decrease is explained by the manufacturing efficiency program of which major part was finalized during 2018.

COGS - Orexo achieved its 2H 2019 cost reduction goal of 35 percent versus 2017 this quarter, ahead of schedule

ZUBSOLV US NET REVENUE GROWTH BY KEY DRIVERS, Q1 2019 VERSUS Q1 2018[1]



[1] Orexo analysis using IMS demand data plus institutional sales

Other operating income and expenses amounted to SEK 7.0 million (2.7) mainly explained by exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency.

Operating profit

Orexo's profitability continued to improve and for the first time Orexo reports a positive EBITDA in a first quarter with SEK 12.0 million due to growing contribution from the US commercial business. When excluding the IP litigation, EBITDA was realized at SEK 60.8 million for the first quarter. An increase from SEK -8.5 million.

The EBIT contribution from US commercial business continues to grow, driven by Zubsolv® growth, COGS reductions and operational leverage in the US enabling revenue growth without any material increase in the operational expenses. The US commercial business contributed with an EBIT improvement to SEK 71.9 million (25.3) equal to an EBIT margin of 44.5 percent (19.3). In local currency EBIT amounted to USD 7.9 million (3.1) for Q1 2019.

The US commercial business contributed with an EBIT improvement to SEK 71.9 million (25.3)

Net financial items and tax

Net financial items amounted to SEK 4.8 million (-3.0). These items are related to financing activities including interest income/expenses and exchange-rate gains/losses derived from foreign currency bank accounts.
For the quarter the bond loan related costs were more than completely offset by earned interest on bank accounts in the US and by a positive exchange rate impact as the SEK/USD rate at the end of Q1, 2019 which was slightly higher than the rate at the end of the previous quarter.

Total tax expenses for the quarter amounted to SEK 8.2 million (-1.1). Tax for the quarter was positively impacted by a SEK 9.3 million adjustment to deferred tax assets related to temporary differences.

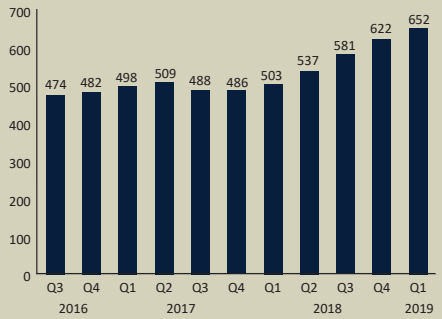
Net earnings

Net earnings amounted to SEK 14.1 million (-25.9). IFRS 16 Leases was implemented during the quarter and it had a negative impact of SEK -0.3 million on net earnings.

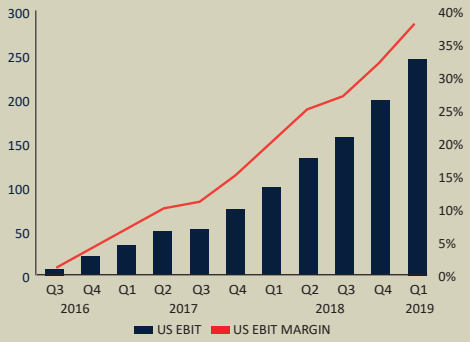
DISTRIBUTION OF TOTAL NET REVENUES

SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec	12 mth Apr 2018-Mar 2019	12 mth Apr 2017-Mar 2018
Zubsolv® US	161.7	131.1	621.5	652.1	502.8
Zubsolv - ex US	-	-	36.2	36.2	5.6
Zubsolv – total	**161.7**	**131.1**	**657.7**	**688.3**	**508.4**
Abstral® royalties	10.9	5.8	118.8	123.9	110.3
Edluar® royalties	1.7	2.8	6.6	5.5	15.5
OX-CLI	-	-	-	-	21.8
Total	**174.3**	**139.7**	**783.1**	**817.7**	**656.0**

ZUBSOLV US NET REVENUES (LTM[1], SEK m)



US EBIT AND US EBIT MARGIN (LTM[1], SEK m)



[1] LTM, Last Twelve Months

Cash, cash flow and net cash/debt

At March 31, 2019, cash and cash equivalents amounted to SEK 647.4 million (437.5) and interest bearing liabilities to SEK 321.0 million (319.5), i.e. a positive net cash position of SEK 326.4 million. The strong cash position enables Orexo to continue to pursue its strategy to progress the development pipeline and to pursue business development opportunities with the target to add more commercial stage products to the US commercial infrastructure.

Cash flow from operating activities for the quarter amounted to SEK 50.9 million (106.3). The lower level compared with same period last year is explained by less contributions from changes in working capital mainly due to already in Q1 2018 achieved inventory reductions.

Investments

Gross investments in tangible and intangible fixed assets amounted to SEK 0.1 million (0.0).

Equity

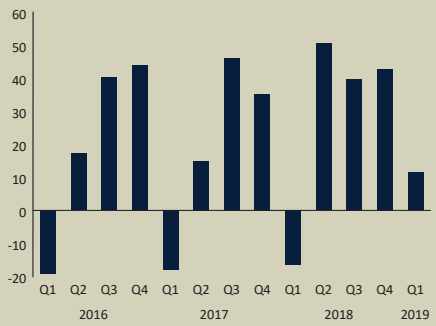
Shareholders' equity at March 31, 2019, was SEK 496.6 million (305.4). The equity/asset ratio was 36.3 percent (29.5).

Parent company

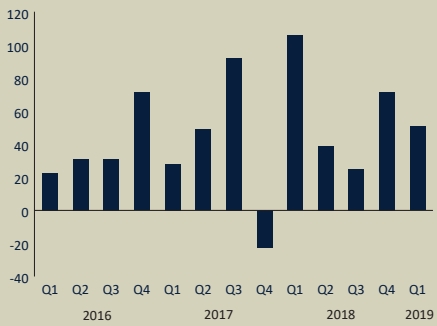
Net revenues amounted to SEK 116.8 million (58.5). Earnings before tax were SEK 19.6 million (-27.0). Investments amounted to SEK 0.1 million (0.0). As of March 31, 2019, cash and cash equivalents in the parent company amounted to SEK 346.5 million (236.7).

Cash and cash equivalents amounted to SEK 647.4 million (437.5)

EBITDA, SEK m

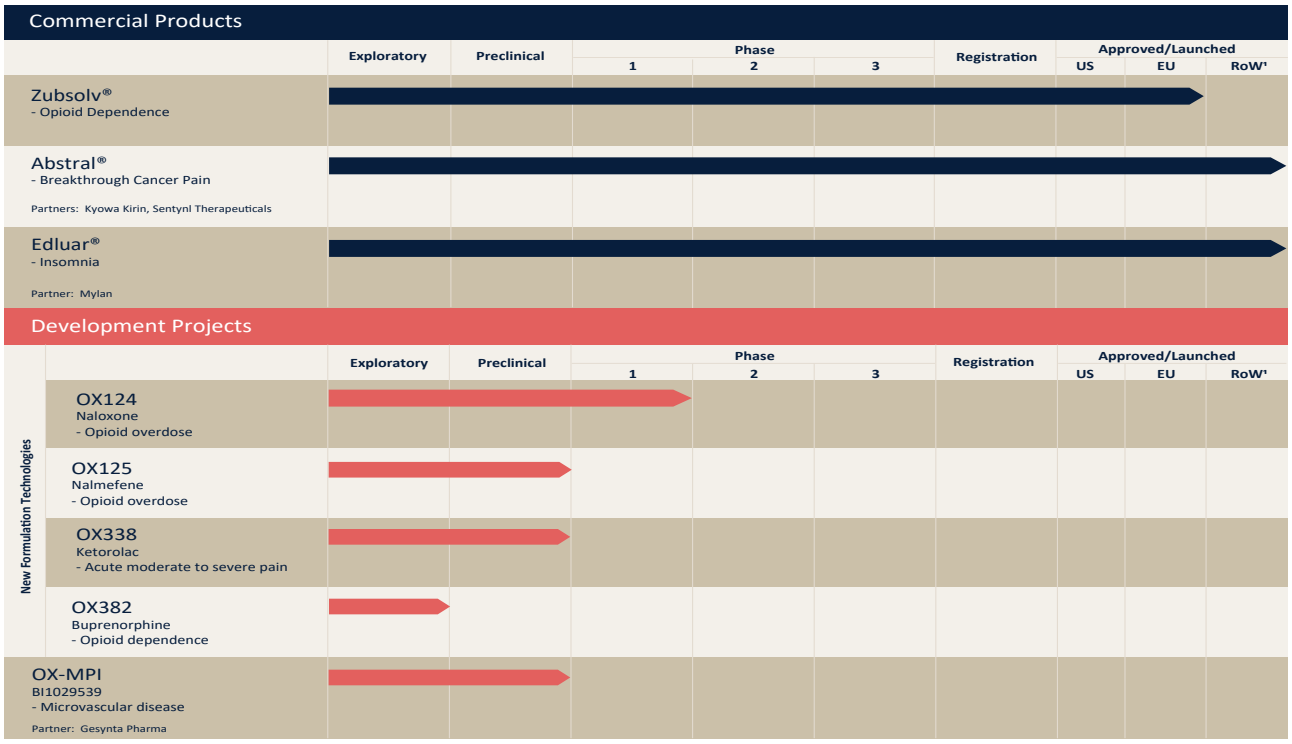


CASH FLOW FROM OPERATING ACTIVITIES, SEK m



Operations

PIPELINE OF COMMERCIAL PRODUCTS AND DEVELOPMENT PROJECTS



Commercial products

Zubsolv® US – treatment of opioid dependence

(buprenorphine/naloxone CIII sublingual tablet)

The market demonstrated a strong growth of 13 percent in volume compared to Q118, and no change over Q418 due to typical market seasonality. The market forecast is continued volume growth, as the epidemic continues to escalate and as more providers begin to treat opioid addiction and also take on an increasing patient load. Four manufacturers launched generic versions of buprenorphine/naloxone film on February 22, including an authorized generic from Indivior through Sandoz AG. While the launch of these generics has had a large impact on Suboxone Film market share and to some extent the market value it has not impacted Zubsolv´s demand. Over 3,000 physicians became newly waivered to accept their first opioid dependence patients this quarter which is the highest number ever recorded.

Nurse practitioners and physicians assistants now total over 11,700 waivered to treat opioid dependency, compared to just 5,600 this quarter last year.

New federal legislation will expand the practitioners who can become certified prescribers, which is expected to continue to improve patient access to treatment and expand the market for Zubsolv.

Zubsolv grew 6 percent over Q118. Compared to Q418, Zubsolv volume declined by 3 percent due to the loss of exclusive access in highly rebated WellCare Medicaid. However, as the rebate has been lowered, Zubsolv´s profitability per prescription has increased. Excluding WellCare volume decline, Zubsolv volume grew 1 percent over Q418 and also beat market growth. Zubsolv has recovered from this decline and reached an all-time high single week volume of 411,000 tablets during the week of March 8, 2019.

Over 3,000 physicians became newly waivered to accept their first opioid dependence patients this quarter which is the highest number ever recorded

[1] Rest of the World, excluding US and Europe

This quarter, Zubsolv® has started to be covered by Blue Cross North Carolina, expanding its best-in-class coverage in the commercial segment and reaching a record high 97 percent coverage. Zubsolv Commercial volume grew 10 percent in Q119 compared to Q118. Due to typical Q1 seasonality within the commercial market, the market declined 2 percent and Zubsolv declined 3 percent in Q119 compared to Q418. Within both Caremark Commercial and Express Scripts Commercial, two competitive formularies where Zubsolv competes with other buprenorphine/naloxone products, Zubsolv grew 2 percent over Q418 and gained share.

In the public segment, Zubsolv access grew from 32 percent in Q418 to 38 percent in Q119. Zubsolv is now accessible in four additional state Medicaid programs, Ohio, Texas, Florida and Alabama. Within these states, Zubsolv has more than doubled its volume in Q119 versus Q418. Over Q118 Zubsolv grew 7 percent in the overall public segment and declined 5 percent versus Q4. Excluding Wellcare, Zubsolv would have grown 8 percent in the segment. Starting in Q2, generic film will have access to the highly rebated Humana Medicare Part D where Zubsolv has been an exclusive product, creating an opportunity for higher profitability due to lower rebates. Starting Q2 Zubsolv has also secured access to Washington DC formulary list.

Zubsolv in geographies outside the United States – opioid dependence

Following Mundipharma's decision to hand back the rights to Zubsolv for all markets outside the United States, Orexo is in advanced negotiations with multiple potential new partners who are interested in commercializing Zubsolv. In parallel, Orexo has taken full control of the supply chain and is working on an initiative that will bring down cost of goods sold significantly compared to the previous set-up. This will make the ex-US business case more attractive for both Orexo and its future partners.

During the quarter, Zubsolv was also approved in Australia, where partnership discussions are ongoing as well.

Development projects

OX124 - opioid overdose with naloxone
OX124 is based on a novel and unique technology developed to provide a rapidly acting naloxone rescue medication with the aim to provide differentiated profile compared to currently marketed products and other products under development.

Naloxone is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose.

Changes during the quarter:
Positive results from a human pharmacokinetic study, OX124-001, were received showing that all formulations of OX124 were well tolerated and displayed substantially higher plasma concentrations of naloxone, sustained duration of elevated plasma concentrations, and equivalent or superior onset time when compared to Narcan®. The next step is to further optimize the formulation and conduct a smaller clinical trial in preparation for a pivotal pharmacokinetic bridging study in 2020.

OX125 - opioid overdose with nalmefene
OX125 is based on a novel and unique technology developed to provide a rapidly acting nalmefene rescue medication with the aim of providing differentiated profile compared to currently marketed products and other products under development.
Nalmefene is a full opioid receptor antagonist which reverses the effects of opioid agonists, including the life threatening respiratory depressant effects occurring in an opioid overdose.

Changes during the quarter:
Following the very positive results from the human pharmacokinetic study for OX124 the development of OX125 has been accelerated.

OX338 - acute moderate to severe pain
OX338 is based on a new sublingual tablet formulation of ketorolac for acute treatment of moderate to severe pain. Ketorolac is a potent NSAID with analgesic effect comparable to many opioids used for short term pain management and can thus replace opioids for many procedures and indications reducing overall opioid consumption.

Changes during the quarter:
Positive study results were received from an in-vivo study supporting advancement into a human pharmacokinetic study, expected to be initiated during 2019.

OX124 - Next step is to further optimize the formulation and conduct a smaller clinical trial in preparation for a pivotal pharmacokinetic bridging study in 2020

OX382 – opioid dependence
OX382 is being developed as an oral, swallowable formulation containing buprenorphine and naloxone for the treatment of opioid dependence. Buprenorphine is a partial opioid receptor agonist used in medically assisted treatment of opioid dependence to alleviate symptoms of withdrawal and naloxone, an opioid receptor antagonist, is part of the formulation as an abuse deterrent.
A swallowable formulation offers several advantages over currently available administrations routes for certain patient groups and treatment settings.

Changes during the quarter:
Results from the in-vivo animal Proof of Concept study conducted during the quarter do not support progressing the project into clinical phase. Options for continued development are currently beeing evaluated.

OX-MPI – Microvascular diseases
Cardiovascular morbidity and mortality are common in chronic inflammatory diseases due to vascular inflammation and endothelial dysfunction.
The lead candidate drug, BI1029539, has been identified as a highly selective anti-inflammatory compound targeting microsomal prostaglandin E synthase (mPGES-1). Selective deletion of mPGES-1 activity leads to anti-inflammatory, vasodilatory and platelet inhibitory effects.
The project is developed by Orexo´s partner Gesynta Pharma AB who owns all the rights to the project.

Changes during the quarter:
OX-MPI is progressing according to plan.
In beginning of April, Gesynta Pharma announced that EUR 6 m was secured in a financing round led by Industrifonden. A consortium consisting of Industrifonden and a group of private life sciences investors provides not only financial strength but also strategic support to Gesynta's development programs and brings the company closer to its next pivotal milestone, initiating the phase 1 clinical program and make the project ready for phase II clinical trials in 2020.

Other information

Outlook 2019

• For 2019 Orexo expects to improve the positive EBITDA on a full year basis
• Orexo believes that the overall volume of Zubsolv® sales in the US in 2019 will increase, despite increased competition from Suboxone® Film generics. However we do expect that a launch of corresponding generics will increase market risk and uncertainty but will also offer opportunities.
• Previous target of achieving 35 percent reduction in the average cost of goods sold (COGS) compared to 2017 in H2 2019 has been updated. New target is a full year effect of 35 percent reduction in COGS compared to 2017 (~30 percent compared to 2018).
• Full year OPEX is expected to stay at the same level as 2018 with approximately SEK 500 million
• The first new partnerships for Zubsolv outside the US is expected to be initiated in 2019
• The outlook is based on current exchange rates (March 2019)

Forward looking statements

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.

Risks and uncertainty factors

Significant risks and uncertainties are presented in the Annual Report for 2018. The continued commercialization of Zubsolv entails risk exposure of an operational nature and Orexo is continuously exposed to risks in relation to development projects and the intellectual property rights.

Uppsala, Sweden, May 2, 2019
Orexo AB (publ.)

Nikolaj Sørensen
President and CEO

This report has not been reviewed by the company's auditors.

Financial reports, notes and key figures

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

SEK million	Notes	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Net revenues	6	174.3	139.7	783.1
Cost of goods sold		-25.3	-48.4	-171.8
Gross profit		**149.0**	**91.3**	**611.4**
Selling expenses		-47.2	-43.3	-191.4
Administrative expenses		-70.1	-27.2	-166.7
Research and development expenses		-37.6	-45.3	-166.8
Other operating income and expenses		7.0	2.7	9.3
Operating earnings		**1.1**	**-21.8**	**95.8**
Net financial items		4.8	-3.0	-3.6
Earnings before tax		**5.9**	**-24.8**	**92.2**
Tax	4	8.2	-1.1	45.7
Net earnings for the period[1]		**14.1**	**-25.9**	**137.9**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Earnings for the period	**14.1**	**-25.9**	**137.9**
Other comprehensive income			
Items that may subsequently be reversed to the statement of operations:			
Exchange-rate differences	3.2	1.2	7.0
Other comprehensive earnings for the period, net after tax	**3.2**	**1.2**	**7.0**
Total comprehensive earnings for the period[1]	**17.3**	**-24.7**	**144.9**
Earnings per share, before dilution, SEK	0.41	-0.75	3.99
Earnings per share, after dilution, SEK	0.40	-0.75	3.93

[1] All equity and earnings for the respective period are attributable to the Parent Company's shareholders

CONDENSED CONSOLIDATED BALANCE SHEET

SEK million	2019 Mar 31	2018 Mar 31	2018 Dec 31
ASSETS			
Fixed assets			
Tangible fixed assets	19.5	19.4	20.0
Intangible fixed assets	99.7	116.6	103.9
Right-of-use assets	68.2	—	—
Deferred tax assets	103.3	31.3	92.8
Other financial assets	10.8	7.3	10.4
Total fixed assets	**301.5**	**174.6**	**227.2**
Current assets			
Inventories	166.4	206.1	173.6
Accounts receivable and other receivables	252.2	217.2	296.1
Cash and cash equivalents	647.4	437.5	589.8
Total current assets	**1,065.9**	**860.8**	**1,059.5**
Total assets	**1,367.4**	**1,035.4**	**1,286.7**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Total shareholders' equity	**496.6**	**305.4**	**476.1**
Long-term liabilities			
Provisions	7.7	5.7	6.5
Long-term liabilities, interest bearing	321.0	319.5	320.6
Lease liabilities, long-term	45.3	—	—
Total long-term liabilities	**373.9**	**325.2**	**327.1**
Current liabilities and provisions			
Provisions	286,5	261.6	265.8
Current liabilities, non-interest bearing	190,5	143.2	217.6
Lease liabilities, current	19.9	—	—
Total current liabilities and provisions	**496.9**	**404.8**	**483.4**
Total liabilities	**870.8**	**730.0**	**810.5**
Total shareholders' equity and liabilities	**1,367.4**	**1,035.4**	**1,286.7**

CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK million	2019 Mar 31	2018 Mar 31	2018 Dec 31
Opening balance, shareholders' equity	**476.1**	**329.1**	**329.1**
Total comprehensive earnings for the period	17.3	-24.7	144.9
Share-based payments	3.1	1.1	2.1
Buy back of shares	—	—	—
New share issue	—	—	0.1
Closing balance, shareholders' equity	**496.6**	**305.4**	**476.1**

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK million	Notes	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Operating earnings		1.1	-21.8	95.8
Interest received		2.0	—	0.5
Interest paid		-3.7	-4.1	-14.8
Income taxes paid		0.0	-3.0	-18.1
Adjustment for non-cash items	2	22.9	60.7	61.9
Cash flow from operating activities before changes in working capital		**22.3**	**31.8**	**127.9**
Changes in working capital		**28.6**	**74.5**	**114.1**
Cash flow from operating activities		**50.9**	**106.3**	**242.0**
Acquisition of tangible and intangible fixed assets		-0.1	—	-3.6
Acquisition of financial assets		—	—	-2.5
Cash flow from investing activities		**-0.1**	**0.0**	**-6.2**
New share issue		0.0	—	0.1
Buy back shares		—	—	-0.1
Repayment of loans		-10.7	—	—
Cash from financing activities		**-10.7**	**0.0**	**0.0**
Cash flow for the period		**40.2**	**106.3**	**235.8**
Cash and cash equivalents at the beginning of the period		**589.8**	**327.9**	**327.9**
Exchange-rate differences in cash and cash equivalents		17.3	3.3	26.1
Changes in cash and cash equivalents		57.4	109.6	261.9
Cash and cash equivalents at the end of the period		**647.4**	**437.5**	**589.8**

Key Figures[1]

Orexo makes use of the key figures below and believe they are useful for readers of the financial reports as a complement to other performance measures when assessing implementation of strategic investments and the Group's ability to meet financial objectives and commitments.

	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
EBIT margin, %	0.6	-15.6	12.2
Return on shareholder equity, %	2.9	-8.2	34.3
Net debt, SEK million	-326.4	-118.0	-269.2
Debt/equity ratio, %	64.6	104.6	67.3
Equity/assets ratio, %	36.3	29.5	37.0
Number of shares, before dilution	34,574,287	34,560,456	34,560,456
Number of shares, after dilution	35,223,304	34,666,623	35,095,980
Earnings per share, before dilution, SEK	0.41	-0.75	3.99
Earnings per share, after dilution, SEK	0.40	-0.75	3.93
Number of employees at the end of the period	131	88	129
Shareholders' equity, SEK million	496.6	305.4	476.1
Capital employed, SEK million	817.6	624.9	796.7
Working capital, SEK million	-78.4	18.5	-13.8

[1] Definitions and reconciliations of key figures are presented on page 20 of this report

CONDENSED PARENT COMPANY STATEMENT OF OPERATIONS

SEK million	Notes	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Net revenues		116.8	58.5	407.6
Cost of goods sold		-27.3	-25.8	-116.2
Gross profit		**89.5**	**32.7**	**291.4**
Selling expenses		-2.9	-0.8	-10.3
Administrative expenses		-62.5	-19.7	-135.2
Research and development costs		-30.5	-39.0	-138.3
Other operating income and expenses		22.1	2.8	50.6
Operating earnings		**15.8**	**-24.0**	**58.1**
Interest income and expenses		-3.4	-3.7	-14.4
Other financial income and expenses		7.2	0.7	8.2
Net financial items		**3.8**	**-3.0**	**-6.1**
Earnings before tax		**19.6**	**-27.0**	**52.0**
Tax	4	—	—	53.3
Earnings for the period		**19.6**	**-27.0**	**105.3**

PARENT COMPANY STATEMENT OF COMPREHENSIVE INCOME

SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Earnings for the period	**19.6**	**-27.0**	**105.3**
Other comprehensive income	—	—	—
Total comprehensive earnings for the period	**19.6**	**-27.0**	**105.3**

CONDENSED PARENT COMPANY BALANCE SHEET

SEK million	2019 Mar 31	2018 Mar 31	2018 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	99.7	116.6	103.9
Tangible fixed assets	19.5	26.8	20.0
Deferred tax assets	60.9	-	60.9
Shares in subsidiaries	152.9	151.1	152.3
Total fixed assets	**332.9**	**294.5**	**337.1**
Current assets			
Inventories	142.5	164.0	155.3
Accounts receivable and other receivables	149.5	97.4	166.8
Cash and bank balances	346.5	236.7	303.2
Total current assets	**638.4**	**498.1**	**625.3**
Total assets	**971.3**	**792.6**	**962.4**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Shareholders' equity	**439.6**	**283.6**	**416.9**
Long-term liabilities			
Other provisions	5.8	4.6	4.9
Bond loan	321.0	319.5	320.6
Total long-term liabilities	**326.7**	**324.1**	**325.5**
Current liabilities			
Accounts payable	20.1	12.2	19.6
Other liabilities	6.1	7.6	25.3
Liabilities to Group companies	136.8	145.7	143.2
Accrued expenses and deferred income	42.0	19.4	32.0
Total current liabilities	**205.0**	**184.9**	**220.1**
Total liabilities	**531.1**	**509.0**	**545.6**
Total shareholders' equity and liabilities	**971.3**	**792.6**	**962.4**

Notes

1. Accounting policies
This report was prepared pursuant to IAS 34. Orexo applies IFRS as approved by the EU.

The accounting policies stated below are in line with those applied in the preparation of the 2018 Annual Report.

The Parent Company's financial statements were prepared in accordance with RFR 2 (Swedish Financial Reporting Board's recommendation) and Chapter 9 of the Swedish Annual Accounts Act.

New and amended accounting policies as of 2019
IFRS 16 Leases has replaced IAS 17. According to the new standard, most leased assets must be recognized in the balance sheet and the lessee shall divide up the cost into interest payments and depreciation of the asset. The standard is applied by the Group as from January 1, 2019. The Parent Company applies the exception rule in RFR 2. Orexo applied the simplified transition method and the main impact on Orexo's accounts arise from the reporting of lease contract for premises. The opening effect on the consolidated balance sheet as of January 1, 2019 was that a lease asset (right-of-use assets) and a lease liability were added, each at SEK 71.4 million. The P&L effect for Q1 2019 amounted to SEK -0.3 million.

ADJUSTMENT FOR IFRS 16

SEK million	2018-12-31	Effect of transition to IFRS 16	2019-01-01
ASSETS			
Right-of-use assets	—	74.1	74.1
Accrued income and prepaid expenses	25.7	-2.7	23.0
Total	**25.7**	**71.4**	**97.1**
SHAREHOLDERS' EQUITY, PROVISIONS AND LIABILITIES			
Lease liabilities, long-term	—	52.0	52.0
Lease liabilities, current	—	19.4	19.4
Total	**0.0**	**71.4**	**71.4**

SEK million	2019 Jan-Mar
Net revenues	—
Cost of goods sold	—
Gross profit	**0.0**
Selling expenses	0.1
Administrative expenses	0.1
Research and development expenses	0.2
Other operating income and expenses	—
Operating earnings	**0.4**
Net financial items	-0.8
Earnings before tax	**-0.4**
Tax	0.1
Net earnings for the period	**-0.3**

2. Cash flow

ADJUSTMENT FOR NON-CASH ITEMS

SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Depreciation/amortization and impairment	10.9	5.2	20.8
Change in provisions	12.4	57.1	45.6
Share based payments	3.1	1.0	2.1
Exchange rate income and expenses	-3.5	-2.6	-6.5
Total	**22.9**	**60.7**	**61.9**

3. Legal disputes

Patent infringement litigation against Actavis for their generic versions of Suboxone® and Subutex® tablets in the US

In March 2017, Orexo filed a patent infringement action in the United States District Court for the District of Delaware against Actavis Elizabeth LLC, Actavis Pharma, Inc., and their parent company Teva (collectively "Actavis"). Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US Patent 8,454,996 (the '996 patent). Actavis's generic version of Suboxone was approved by the FDA in February 2013 and their generic version of Subutex in February 2015. Orexo was seeking compensation for damages caused by Actavis's infringement of the '996 patent since the year of approval of these two products. On March 29 the District Court of Delaware declared that Actavis does not infringes patent ´996 with their generic versions of Suboxone and Subutex. Orexo has decided to appeal the decision.

4. Deferred tax

New Swedish corporate tax rates have been announced with 21.4 percent from January 1, 2019, and 20.6 percent from January 1, 2021. In line with IFRS which on this area is based on a principle that changes in tax rates should be incorporated into the accounting for the relevant tax positions immediately upon enactment, the company has performed a tax analysis. The tax-loss carry-forward in the Group amounts to SEK 1,414 million as of December 31 2018 and refers to the Swedish companies. Deferred tax assets of SEK 60.9 million for tax-loss carry-forwards have been capitalized as per December 31, 2018, for the part of these tax-loss carry-forwards which the company has assessed as fulfilling the recognition requirements of IAS 12. There is no time limit for when the remaining loss carryforwards can be utilized.

The rest of the tax effect of the Group's temporary differences are related to non-deductible current provisions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions in the company's US operations.

5. Financial instruments

The Group's financial instruments consists of current receivables, non-current receivables, cash and cash equivalents, current non-interest bearing liabilities, current interest-bearing liabilities and long-term interest-bearing liabilities. The financial instruments held by the group are recognized at amortized cost using the effective interest method. The group does not hold any financial instruments which are reported at fair value. The fair value of financial instruments held at the balance sheet date is significantly the same as the book value.

6. Related parties

There were no significant related parties transactions during the period.

7. Important events after the period

No important events after the period.

8. Revenue from contracts with customers

SEK million	2019 Jan-Mar			
Type of revenue	**Zubsolv®**	**Abstral®**	**Edluar®**	**Total**
Sales, products	161.7	—	—	**161.7**
Royalties	—	10.9	1.7	**12.6**
Milestones	—	—	—	**0.0**
Total revenue from contracts with customers	**161.7**	**10.9**	**1.7**	**174.3**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**Total**
US	161.7	1.2	0.4	**163.3**
EU	—	6.0	0.6	**6.5**
Rest of the world	—	3.7	0.8	**4.5**
Total revenue from contracts with customers	**161.7**	**10.9**	**1.7**	**174.3**

SEK million	2018 Jan-Mar			
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**Total**
Sales, products	131.1	—	—	**131.1**
Royalties	—	5.8	2.8	**8.6**
Milestones	—	—	—	**0.0**
Total revenue from contracts with customers	**131.1**	**5.8**	**2.8**	**139.7**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**Total**
US	131.1	1.5	0.7	**133.3**
EU	—	-1.2	0.4	**-0.8**
Rest of the world	—	5.5	1.7	**7.2**
Total revenue from contracts with customers	**131.1**	**5.8**	**2.8**	**139.7**

SEK million	2018 Jan-Dec			
Type of revenue	**Zubsolv**	**Abstral**	**Edluar**	**Total**
Sales, products	626.9	—	—	**626.9**
Royalties	0.1	118.8	6.6	**125.4**
Milestones	30.8	—	—	**30.8**
Total revenue from contracts with customers	**657.8**	**118.8**	**6.6**	**783.1**
Geographical markets	**Zubsolv**	**Abstral**	**Edluar**	**Total**
US	621.5	4.8	0.7	**627.0**
EU	36.2	90.1	1.2	**127.5**
Rest of the world	—	24.0	4.7	**28.6**
Total revenue from contracts with customers	**657.8**	**118.8**	**6.6**	**783.1**

Geographical distribution of royalties and milestones are based on the counterparts registered office.

Definitions and reconciliations of key figures

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION PER SHARE ARE DEFINED AS FOLLOWS

Margins	Definition/calculation	Purpose
Gross margin	Gross profit divided by net revenues	Gross Margin is used to measure the relative direct profitability from sold products
Operating margin (EBIT margin)	Operating earnings as a percentage of net revenues	Operating profit margin is used for measuring the operational profitability
US EBIT margin	US EBIT (SEK) as a percentage of US net revenues (SEK)	US EBIT margin is used for measuring the operational profitability
Return	**Definition/calculation**	**Purpose**
Return on equity	Net earnings for the period as a percentage of average shareholders' equity	Return on equity is used to measure profit generation, given the resources attributable to the owners of the Parent Company
Capital structure	**Definition/calculation**	**Purpose**
Net Debt	Current and long-term interest-bearing liabilities including pension liabilities, less cash and cash equivalents	The net debt is used as an indication of the ability to pay off all debts if these became due simultaneously on the day of calculation, using only available cash and cash equivalents
Debt/equity ratio	Interest bearing liabilities divided by shareholders' equity	The debt/equity ratio measures how much debt a company is using to finance its assets relative to the amount of value represented in shareholder's equity.
Equity/assets ratio	Shareholders' equity as a percentage of total assets	This ratio is an indicator of the company's leverage used to finance the firm
Working capital	Current assets excluding cash and cash equivalents less current liabilities excluding interest bearing liabilities	Working capital is used to measure the company's ability, besides cash and cash equivalents and interest bearing liabilities, to meet current operational obligations
Capital employed	Interest-bearing liabilities and shareholders' equity	Capital employed measures the amount of capital used and serves as input for the return on capital employed
Gross investments	Value of investment before amortization	Gross investments is a measure of the company's investments in tangible and intangible fixed assets
Data per share	**Definition/calculation**	**Purpose**
Number of shares after dilution	Shares at the end of the period adjusted for the dilutive effect of potential shares	Is used to calculate earnings per share after dilution
Earnings per share, before dilution	Net earnings for the period after tax divided by the average number of shares outstanding before dilution during the period	The earnings per share before dilution measures the amount of net profit that is available for payment to its shareholders per share before dilution
Earnings per share, after dilution	Net earnings for the period after tax divided by the average number of shares outstanding after dilution during the period	The earnings per share after dilution measures the amount of net profit that is available for payment to its shareholders per share after dilution
Other definitions	**Definition/calculation**	**Purpose**
Gross Revenues	Grand total of all invoiced sales transactions reported in a period, without any deductions	Reflects the company's invoiced revenues without any deductions
Net Revenues	Gross Revenues less deductions for sales rebates, sales allowances, distribution, sales returns and other relevant deductions	Reflects the company's invoiced revenues after deductions
Gross to net ratio	Net Revenues divided by Gross Revenues	Reflects a relative portion of net revenue as percentage of gross revenue
Operating expenses	An expense incurred in daily operating activities. Expense related to financing is not considered part of daily operating activities.	Operating expenses reflect costs for selling, administration, research and development, depreciation and other operating income and operating expenses
US EBIT (SEK)	US net revenues (SEK) less consolidated US cost of goods sold (SEK) less US operating expenses (SEK)	Profit measure which illustrates direct contribution (SEK) from US business
EBIT	Earnings before net financial items and tax, the same as Operating earnings	This measure enables the profitability to be compared across locations where corporate taxes differ and irrespective the financing structure of the company
EBITDA	Earnings before interest, taxes, depreciation and amortization. EBIT plus depreciation	Profit measure which is more closely correlated with cash flow as non-cash items like Depreciation and Amortization are excluded
Earnings after financial items	Operating earnings (EBIT) plus financial income less financial expense	Earnings after financial items reflects earnings after, any results from participations in Group and associated companies, results from securities and receivables that fall within the type of fixed assets as well as interest expenses and interest income

KEY FIGURES AND CERTAIN OTHER OPERATING INFORMATION ARE RECONCILED AS FOLLOWS

EBITDA SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
EBIT	1.1	-21.8	95.8
Depreciation and amortization	10.9	5.2	20.8
EBITDA	**12.0**	**-16.6**	**116.6**
IP litigation costs	48.8	8.2	82.8
EBITDA excluding IP litigation costs	**60.8**	**-8.5**	**199.4**

RETURN ON SHAREHOLDERS' EQUITY	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Shareholders' equity beginning balance	476.1	329.1	329.1
Shareholders' equity ending balance	496.6	305.4	476.1
Average shareholders' equity	486.4	317.3	402.6
Net earnings	14.1	-25.9	137.9
Return on shareholders' equity %	**2.9**	**-8.2**	**34.3**

OPERATING EXPENSES SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Selling expenses	-47.2	-43.3	-191.4
Administrative expenses	-70.1	-27.2	-166.7
Research and development costs	-37.6	-45.3	-166.8
Other operating income and expenses	7.0	2.7	9.3
Operating expenses	**-147.9**	**-113.1**	**-515.6**

GROSS INVESTMENTS SEK million	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Investments in tangible fixed assets	0.1	-	2.9
Investments in intangible fixed assets	-	-	0.7
Gross investments	**0.1**	**0.0**	**3.6**

US EBIT SEK million and EBIT margin %	2019 Jan-Mar	2018 Jan-Mar	2018 Jan-Dec
Consolidated operating earnings	1.1	-21.8	95.8
Non US related items impacting operating earnings	-70.8	-47.1	-102.5
US EBIT	**71.9**	**25.3**	**198.3**
US EBIT margin %	**44.5**	**19.3**	**31.9**

Glossary

Alfentanil
A potent synthetic opioid analgesic drug, used for anesthesia in surgery
American Depositary Receipt (ADR)
An instrument that is issued by a depositary bank that represents ownership of a company's underlying shares. ADR programs are created to facilitate US investors to hold shares in non-US companies and trade them in the same way as US securities.
ANDA
An Abbreviated New Drug Application (ANDA) is an application for a US generic drug approval for an existing licensed medication or approved drug
Anesthesia
Procedure for lowering a patient's consciousness to enable a Medical procedure to proceed without pain for the patient
Breakthrough pain
A short, intensive period of pain that occurs in addition to chronic levels of long-term pain even though these are treated by regular painkillers
Buprenorphine
A potent opioid partial agonist first used as a pain-relieving substance, but now most commonly used to help patients withdraw from more addictive opioid drugs such as morphine
CARA
The Comprehensive Addiction and Recovery Act (CARA) became law in the US in July 2016. CARA authorizes a series of grants aimed at among other things developing treatment programs which further expands buprenorphine prescribing rights to nurse practitioners and physician assistants
Cash & vouchers segment
One of the three distinct payer segments in the US market for treatment of opioid dependence. In this segment, the patient is paying for the prescriptions out of pocket
CHMP
The Committee for Medicinal Products for Human Use
CLI
Cysteinyl Leukotriene Inhibitor
Clinical studies/Clinical trials
Studies of the safety and efficacy of a drug in human beings
Commercial segment
One of the three distinct payer segments in the US market for treatment of opioid dependence. The commercial segment is funded by private insurances or employers
Drug delivery
The process through which a pharmaceutical may be introduced to the patient that enables the active compound to function as intended
EMA
The European Medicine Agency
FDA
The US Food and Drug Administration
Fentanyl
An opioid with a similar effect on human patients as morphine. Used mainly within anesthesia and analgesia
GMP
Good Manufacturing Practice
HHS
The US Department of Health and Human Services
In Vitro studies
In an in vitro study; living matter is examined outside of its natural context e.g. in a test-tube
IP
Intellectual Properties
Naloxone
An opioid antagonist used to counter the effects of opioids
LTM
Last Twelve Months
NSAID
Non-steroid anti-inflammatory drugs which are active against pain, inflammation and fever
NTRx
Tablets per prescription divided by 30
Opioids
Collective term for compounds that act via opioid receptors on nerve cells, mainly in the central nervous system
PBM (Pharmacy Benefit Manager)
Responsible for management of costs associated with prescription pharmaceuticals and recommendations on behalf of insurance companies and employers in the US
PGE
Prostaglandin (PG) E2 – biologically active mediator derived from arachidonic acid and involved in inflammatory conditions
Phase I studies
Studies mainly of the safety of a drug. Performed on healthy human volunteers
Phase II studies
Studies of the safety and efficacy of a drug in appropriate doses. Performed on a limited number of patients
Phase III studies
Studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients
Preclinical development/Preclinical studies
Studies of the safety and efficacy of a drug prior to evaluation in humans. Can be performed on animals and in various cell systems
Proof of Concept studies
A Proof of Concept study is performed to get a first indication of an idea's practical feasibility
Public segment
One of three distinct payer segments in the US market for treatment of opioid dependence. The public segment covers state and federal funded reimbursement programs i.e. Managed Medicaid, FFS Medicaid, Medicare Part D
Reimbursement
Contribution from the state or insurance company in order to reduce the price of drugs / treatment for the patient
Sublingual
Under the tongue
Zolpidem
A pharmaceutical substance used to treat temporary or short-term insomnia