https://www.sec.gov/Archives/edgar/data/849043/000084904306000002/f8k021606.htm
8-K 1 f8k021606.htm
FORM 8-K
February 16, 2006
NEUROGEN CORPORATION
VR1 PHASE I CLINICAL TRIALS $2 MILLION FROM MERCK

On February 16, 2006, Neurogen Corporation issued a press release announcing that Merck & Co., Inc. has commenced Phase I clinical trials of NGD-8243, a leading drug candidate for treating pain, and one of several drug candidates being developed as the result of the companies' exclusive worldwide alliance to develop oral therapeutics targeting the VR1 receptor. The Phase I clinical trial being conducted by Merck in Europe is a randomized, double-blind, placebo-controlled evaluation of the safety and pharmacokinetics of single ascending oral doses of NGD-8243 in healthy volunteers. **The initiation of Phase I studies triggers a milestone payment of $2 million from Merck to Neurogen**.

https://www.sec.gov/Archives/edgar/data/352747/000143774911005563/ex99-1.htm
EX-99.1 2 ex99-1.htm EXHIBIT 99.1
Exhibit 99.1
August 8, 2011
Unigene Laboratories, Inc
Unigene and GSK Enter Development Services and Clinical Supply Agreement in Preparation of Potential Phase 3 Study of Oral PTH for the Treatment of Osteoporosis in Postmenopausal Women

On December 10, 2010, Unigene entered into an amended and restated exclusive worldwide license agreement with GSK to develop and commercialize an oral formulation of a recombinantly produced PTH analog for the treatment of osteoporosis in postmenopausal women. Under the terms of the amended and restated agreement, Unigene is responsible for the manufacture of the PTH and the conduct of the Phase 2 study. **The Company received an upfront payment of $4 million in December to cover costs associated with the Phase 2 study, and also received an additional $4 million payment in May upon completion of Phase 2 patient enrollment**, and is eligible to receive further payments of up to approximately $140 million based on the achievement of regulatory and commercialization milestones. In addition, Unigene is eligible to receive tiered double-digit royalties in the low-to-mid teens on global sales. Once the Phase 2 study has been completed and based on a review of the data, GSK may elect to assume responsibility for all future development and commercialization of the product.

https://www.sec.gov/Archives/edgar/data/1399250/000114420413050290/v354767_ex99-6.htm
EX-99.6 7 v354767_ex99-6.htm LETTER TO SHAREHOLDERS
Exhibit 99.6
September 9, 2011

Transition
UNTITLED

In exercising the option to assume all TT-401 rights, Lilly also paid Transition a US$7 million milestone payment. Under the option exercise, **Lilly will perform and fund all future development and commercialization activities. Transition will provide one-time funding of US$14 million during the performance of the TT-401 Phase 2 study by Lilly**. If TT-401 is successfully commercialized, Transition will be eligible to receive approximately US$240 million in additional milestone payments. Transition will also be eligible to receive a double-digit royalty on sales of TT-401 products and a low single digit royalty on related compounds.

https://www.sec.gov/Archives/edgar/data/1070698/000107069811000148/raptorpressrelease121911.htm
EX-99.1 2 raptorpressrelease121911.htm EXHIBIT 99.1
PRESS RELEASE
December 19, 2011
Raptor Pharmaceutical Corp.
Raptor Pharmaceutical Corp. Signs Collaborative Research and Development Agreement with NIDDK on Phase 2b Clinical Trial of RP104 (DR Cysteamine Tablets) in Non-alcoholic Steatohepatitis (“NASH”)

Raptor estimates the total cost of the CyNCh trial to be in the range of $14-$16 million. Under the CRADA agreement, Raptor will fund a total of $6 million of the cost of the trial, in addition to providing clinical trial materials and drug manufacturing/quality support estimated at approximately $1 million. The remainder of the funding will come from NIDDK. Raptor holds worldwide, exclusive licenses from UC San Diego to patents relating to use of cysteamine in NAFLD and NASH. Under this CRADA collaboration, Raptor will retain exclusive development and commercial rights to the clinical data resulting from the CyNCh trial.

https://www.sec.gov/Archives/edgar/data/1034842/000110465912016254/a12-6714_1ex99d1.htm
EX-99.1 2 a12-6714_1ex99d1.htm
EX-99.1
March 6, 2012
Rigel Pharmaceuticals, Inc
Rigel Announces Fourth Quarter and Year End 2011 Financial Results

The decrease in contract revenue from collaborations in 2011 was mainly due to the $100.0 million upfront payment received in 2010 pursuant to the exclusive worldwide license agreement with AstraZeneca AB (AZ) for fostamatinib, **as well as $25.0 million in revenues earned from AZ in 2010 for the initiation of the Phase 3 clinical trial program with fostamatinib in**

patients with rheumatoid arthritis (RA) and the completion of the transfer of the fostamatinib open label extension study to AZ.

https://www.sec.gov/Archives/edgar/data/1000694/000114420414014965/R17.htm
XML 77 R17.htm IDEA: XBRL DOCUMENT
Dec. 31, 2013
Novavax
U.S. Government Agreement, Joint Venture and Collaborations [Abstract], Note 8 - U.S. Government Agreement, Joint Venture and Collaborations

In February 2011, the Company was awarded a contract from HHS BARDA valued at $97 million for the first three-year base-period, which was extended in February 2014 by seven months to September 2014, with an HHS BARDA option for an additional two-year period valued at $79 million. This extension is intended to allow the Company to continue to access the remainder of the base-period funding. The HHS BARDA contract award provides significant funding for the Company's ongoing clinical development and product scale-up of both its seasonal and pandemic influenza vaccine candidates.

The Company recognized revenue of approximately $17.4 million in 2013, and has recognized approximately $52 million in revenue since the inception of the contract. **In connection with the recent amendment of the HHS BARDA contract, the Company recorded revenue of $2.7 million in the fourth quarter of 2013 relating to manufacturing and other activities that support the Phase 1/2 clinical trial of its H7N9 candidate and Matrix-M adjuvant, which began in the first quarter of 2014.**

Under certain circumstances, HHS BARDA reimbursements may be delayed or even potentially withheld. In March 2012, the Company decided to conduct a Phase 2 clinical trial of its quadrivalent seasonal influenza vaccine candidate ("205 Trial") under its existing U.S. investigational new drug application ("IND") for its trivalent seasonal influenza vaccine candidate as opposed to waiting to conduct this clinical trial under a new IND for its quadrivalent vaccine candidate ("Quadrivalent IND"). Based on the Company's discussions with HHS BARDA in 2012, the outside clinical trial costs for the 205 Trial may only be submitted for reimbursement to HHS BARDA and recorded as revenue by the Company after it submits the clinical trial data in a future Quadrivalent IND. The submission of the Quadrivalent IND is expected shortly before the Company initiates the next Phase 2 dose-confirmatory clinical trial, which is currently expected in the fourth quarter of 2014. **The outside clinical trial costs of the 205 Trial conducted in 2012 total $2.9 million.** These costs have been recorded as an expense and are included in cost of government contracts revenue.

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EX-99.1 2 ex99_1.htm EXHIBIT 99.1
Exhibit 99.1

August 5, 2014
Discovery Laboratories, Inc.
Discovery Labs Reports Second Quarter 2014 Financial Results

During the second quarter of 2014, sales of SURFAXIN to the Company's specialty distributor were approximately $114,000 and demand sales into hospitals were $72,000. In accordance with the Company's revenue recognition policy, for the second quarter of 2014, the Company recognized $42,000 in revenue for sales of SURFAXIN. **The Company also recognized $1.1 million in grant revenue under a $1.9 million Fast Track SBIR Grant from the NHLBI of the NIH to provide support for the ongoing phase 2a clinical trial for AEROSURF**. The remaining $0.8 million available under the grant is expected to be received by the end of 2014.

https://www.sec.gov/Archives/edgar/data/832489/000143774914014670/ex99-1.htm
EX-99 2 ex99-1.htm EXHIBIT 99.1
Exhibit 99.1
August 7, 2014
GeoVax Labs, Inc.
GeoVax Reports 2014 Second Quarter Financial Results and Provides Corporate Update

Preventive HIV Vaccine Program: All of the human clinical trials of GeoVax's preventive HIV vaccines have been conducted by the HIV Vaccine Trials Network (HVTN) with funding from the NIH. The most recent of these clinical trials (HVTN 094), a Phase 1 study of GOVX-B21, was completed in late 2013. Based on analysis of all available data generated to date, GeoVax is advancing GOVX-B11 to the next stage of human clinical testing, and is in planning discussions with the HVTN and NIH for a Phase 2b efficacy trial. **GeoVax expects the Phase 2b trial to involve as many as 4,000 subjects (vaccine + placebo) with an estimated cost in excess of $50 million**. While GeoVax expects the NIH to fund this trial, any formal commitment may not occur until 2015. In advance of this commitment, GeoVax has requested approximately $3 million for the production of the DNA component of its vaccine regimen in sufficient quantities for the proposed Phase 2b trial. The Company expects a response from the NIH to this request during the third quarter of 2014. Should this funding be unavailable, GeoVax will seek other sources for funding vaccine production.

https://www.sec.gov/Archives/edgar/data/1567514/000119312514305711/d774909dex991.htm
EX-99.1 2 d774909dex991.htm
EX-99.1
August 12, 2014
Intra-Cellular Therapies, Inc.
Intra-Cellular Therapies Reports Financial Results for Second Quarter Ended June 30, 2014

Research and development (R&D) expenses for the second quarter of 2014 were $2.7 million, compared to $7.8 million for the second quarter of 2013. **The decrease of $5.1 million is due**

almost exclusively to costs associated with outside clinical testing for our Phase 2 clinical trials of ITI-007 that was completed in late 2013, with no related costs incurred in 2014. Partially offsetting this decrease were expenses of approximately $1.0 million relating to manufacturing and other clinical and non-clinical testing of our ITI-007 product candidate.

https://www.sec.gov/Archives/edgar/data/1621443/000110465917068241/a17-27035_1ex99d1.htm
EX-99.1 2 a17-27035_1ex99d1.htm
EX-99.1
November 14, 2014
Zynerba Pharmaceuticals, Inc
Zynerba Pharmaceuticals Reports Third Quarter 2017 Financial Results and Operational Highlights

The Company believes that the cash and cash equivalent position of **$66.3 million as of September 30, 2017 is sufficient to develop five Phase 3-ready programs and initiate at least one pivotal program** and fund operations and capital requirements into 2019.

https://www.sec.gov/Archives/edgar/data/1553846/000117184315001738/newsrelease.htm
EX-99 2 newsrelease.htm PRESS RELEASE
EXHIBIT 99.1
March 31, 2015
RedHill Biopharma Ltd.
RedHill Biopharma Acquires Phase II First-in-Class Oral Small Molecule SK2 Inhibitor From Apogee Biotech

Apogee received cumulative funding exceeding $14 million to support the development of ABC294640, primarily through grants and contracts from U.S. federal and state government agencies such as the NIH Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program, including funding from the National Cancer Institute (NCI), the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA), the Department of Defense (DoD), the FDA Office of Orphan Products Development and the Pennsylvania Department of Health.

A Phase Ib/II clinical study with ABC294640 for refractory/relapsed diffuse large B cell lymphoma (DLBCL) is planned to commence in the second quarter of 2015 and will be funded by a $1.5 million grant awarded by the National Cancer Institute under the NIH SBIR/STTR program to Apogee in conjunction with the Louisiana State University Health Science Center. The study will include approximately **30 patients** and is intended to assess the tolerability of ABC294640 within the DLBCL population, as well as provide a preliminary evaluation of efficacy. A second Phase II clinical study of ABC294640 for the treatment of multiple myeloma is planned, subject to funding by a pending grant from the National Cancer Institute. A third Phase II clinical study is being planned by RedHill in order to evaluate

ABC294640 as a radio-protectant and radiation enhancer in cancer patients undergoing radiotherapy.

https://www.sec.gov/Archives/edgar/data/1419600/000119312515280981/d56782dex991.htm
EX-99.1 2 d56782dex991.htm EX-99.1
August 6, 2015
Flexion Therapeutics, Inc.
Flexion Therapeutics Reports Second-Quarter 2015 Financial Results

In April 2015, we announced that the DoD awarded us a **grant worth approximately $2 million and that, in connection with the DoD grant, we initiated a Phase 2 clinical trial** investigating FX006 as a treatment for OA pain in active military and medically retired veterans with post-traumatic OA of the knee.

https://www.sec.gov/Archives/edgar/data/882796/000117184315006102/R8.htm
XML 27 R8.htm IDEA: XBRL DOCUMENT
September 30, 2015
BIOCRYST PHARMACEUTICALS INC
Note 3 — Collaborative and Other Research and Development Contracts

On March 31, 2015, the Company announced that **the Biomedical Research and Development Authority within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response awarded BioCryst a contract for the continued development of BCX4430** as a potential treatment for diseases caused by RNA pathogens, including filoviruses. **This BARDA/HHS contract includes a base contract of $13,314 to support BCX4430 drug manufacturing, as well as $22,855 in additional development options that can be exercised by the government, bringing the potential value of the contract to $36,169.** As of September 30, 2015, a total of $16,300 has been awarded under exercised options within this contract.

National Institute of Allergy and Infectious Diseases ("NIAID/HHS"). **In September 2013, NIAID/HHS contracted with the Company for the development of BCX4430** as a treatment for Marburg virus disease. **NIAID/HHS, part of the National Institutes of Health, made an initial award of $5,000 to the Company. The total funding under this contract as of September 30, 2015 could be up to $34,002, if all contract options are exercised by NIAID/HHS**, over a five year period. **The goals of this contract, including amendments, are to file IND applications for intravenous and intramuscular BCX4430 for the treatment of Marburg virus disease, to study BCX4430 as a treatment for Ebola virus disease and to conduct an initial Phase 1 human clinical trial. As of September 30, 2015, a total of $29,875 has been awarded** under exercised options within this contract. BCX4430 is the lead compound in the Company's BSAV research program.

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EX-99.1 2 v424618_ex99-1.htm EXHIBIT 99.1
Exhibit 99.1
November 12, 2015
Capricor Therapeutics, Inc.
Capricor Therapeutics Reports Third Quarter 2015 Business & Financial Highlights

The Phase I DYNAMIC trial is evaluating CDCs (CAP-1002) in patients with advanced heart failure. The trial enrolled 14 patients with either ischemic or non-ischemic dilated cardiomyopathy with left ventricular ejection fraction (LVEF) of 35% or below and New York Heart Association (NYHA) Class III or Ambulatory Class IV heart failure. Suitable patients underwent sequential intracoronary infusion of CAP-1002 in up to three coronary territories. The triple vessel infusion was designed to deliver cells to wide areas of myocardium since patients with advanced heart failure have significant fibrosis in all areas of the heart. **The Phase I trial is being funded in part through a grant of approximately $3.0 million from the National Institutes of Health (NIH).**

https://www.sec.gov/Archives/edgar/data/1600620/000115752315003852/a51224700ex99_1.htm
EX-99.1 2 a51224700ex99_1.htm
EXHIBIT 99.1
November 13, 2015
Aurinia Pharmaceuticals Inc.
Aurinia Reports Third Quarter 2015 Financial Results

For the third quarter ended September 30, 2015, the Company reported a consolidated net loss of $5.2 million or $0.16 per common share, as compared to a restated consolidated net income of $2.8 million or $0.08 per fully diluted common share for the same period in 2014. **The change was primarily attributable to an increase of $2.2 million in Phase 2b LN clinical trial costs** and a decrease of $4.1 million in the non-cash gain on the quarterly fair value revaluation of the derivative warrant liability for the three months ended September 30, 2015 compared to the same period in 2014. In addition the 2014 comparative figure reflected a gain on extinguishment of warrant liability of $1.75 million. There was no similar item in 2015.

https://www.sec.gov/Archives/edgar/data/1293971/000156459015011237/blue-ex991_46.htm
EX-99.1 2 blue-ex991_46.htm EX-99.1
Exhibit 99.1
December 3, 2015
bluebird bio
bluebird bio and ViroMed Enter into License Agreement for Novel Antibodies to Develop Chimeric Antigen Receptor T Cell Therapy

Under the terms of the agreement, ViroMed will provide bluebird bio exclusive rights to its novel humanized antibody to the target, and bluebird bio will leverage its proprietary lentiviral gene therapy platform and CAR T capabilities to **develop CAR T therapies** against the target. **Financial terms of the agreement include a $1 million upfront payment and subsequent milestone payments to ViroMed, which together could total over $48 million per licensed product if certain development and regulatory milestones are achieved**. ViroMed is also eligible to receive tiered royalties on product sales. bluebird bio will conduct and fund clinical development as well as regulatory and commercial activities.

https://www.sec.gov/Archives/edgar/data/1301501/000130150116000080/R12.htm
XML 27 R12.htm IDEA: XBRL DOCUMENT
June 30, 2016
Achaogen Inc
Government Contracts

In August 2010, t**he Company was awarded a contract with the Biomedical Advanced Research and Development Authority ("BARDA") for the development, manufacturing, nonclinical and clinical evaluation of, and regulatory filings for, plazomicin** as a countermeasure for disease caused by antibiotic-resistant pathogens and biothreats. T**he original contract included committed funding of $27,600,000 for the first two years of the contract** and subsequent options exercisable by BARDA to provide additional funding. In September 2012, **BARDA exercised an additional $15,798,000 contract option ("Option 1"), which increased the total contract committed funding to $43,398,000 through March 2014. In April 2013, the Company was awarded an additional $60,410,000 under the contract to support its Phase 3 clinical trial of plazomicin ("Option 2") to increase the total committed funding under this contract to $103,808,000.** On May 26, 2016, the Company was awarded an additional $20 million ("Option 3") under the contract to support its Phase 3 EPIC trial of plazomicin. This brings the total committed funding under the contract to $123,808,000. The Company recorded contract revenue of $8,510,000 and $4,876,000 under this agreement during the three-month periods ended June 30, 2016 and 2015, respectively, and $13,780,000 and $9,717,000 during the six-month periods ended June 30, 2016 and 2015, respectively

https://www.sec.gov/Archives/edgar/data/1534120/000155837016006680/cerc-20160720ex9911b330d.htm
EX-99.1 2 cerc-20160720ex9911b330d.htm EX-99.1
Exhibit 99.1
July 20, 2016
Cerecor
Grant to Fund CERC-501 Development for Alcohol Use Disorder

Cerecor Inc. (NASDAQ: CERC), a clinical-stage biopharmaceutical company developing treatments to make a difference in the lives of patients with neurological and psychiatric disorders, today announced that it has been awarded a grant (award number U44AA025253) from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) at the National Institutes of Health (NIH). The **grant of $1.0 million provides Cerecor with additional resources to progress the development of CERC-501 for the treatment of alcohol use disorder (AUD)**. Upon successful completion of the development activities covered under this grant, Cerecor will have the opportunity to apply for continued funding.

Cerecor is a biopharmaceutical company that is developing innovative drugs that make a difference in the lives of patients with neurological and psychiatric diseases. **Cerecor is currently pursuing the development of two clinical Phase 2-stage product candidates: CERC-501** and CERC-301, an oral, NR2B-specific, NMDA receptor antagonist. Cerecor is currently conducting a Phase 2 study of CERC-301 as an adjunctive treatment of MDD and expects to announce results from that study in the first half of 2017. In addition, Cerecor is conducting preclinical testing of CERC-406, a brain penetrant COMT inhibitor with potential procognitive activity. For more information about the company and its products, please visit www.cerecor.com or contact Mariam E. Morris, Chief Financial Officer, at (443) 304-8002.

https://www.sec.gov/Archives/edgar/data/1094038/000119312516710452/d259737dex992.htm
EX-99.2 4 d259737dex992.htm PRESS RELEASE
Exhibit 99.2
September 6, 2016
TapImmune Issues
Multiple Phase 2 Trials, over $9 Million in New Funding & NASDAQ Uplisting Application

The **$9 million cash influx**, combined with the elimination of the derivative liability creates a balance sheet for TapImmune that enabled us to apply for an uplisting of our common stock to the NASDAQ Capital Market. **It also provides available cash to execute on the 4 Phase 2 trials of our lead clinical candidate TPIV 200, while also providing funding for the continued advancement of our second clinical candidate TPIV 110, slated to enter Phase 2**.

We anticipate this **Phase 2 study of TPIV 200** in the treatment of triple negative breast cancer, conducted by the Mayo Clinic and sponsored by the U.S. Department of Defense (DOD), will begin to enroll patients in the fourth quarter of this year. The anticipated **280 patient study** will be led by Dr. Keith Knutson of the Mayo Clinic in Jacksonville, Florida. Dr. Knutson is the inventor of the technology and an advisor to TapImmune. **While TapImmune is supplying doses of TPIV 200 for the trial, the remaining costs associated with conducting this study will be funded by a $13.3 million grant made by the DOD to the Mayo Clinic**.

https://www.sec.gov/Archives/edgar/data/725363/000165495416004905/R16.htm
XML 25 R16.htm IDEA: XBRL DOCUMENT

September 30, 2016
Cel-Sci Corporation
Commitments and Contingencies Disclosure [Abstract]

The Company estimates that the total remaining cash cost of the Phase 3 clinical trial, excluding any costs that will be paid by CEL'SCI's partners, would be approximately $12.1 million after September 30, 2016. This is based on the executed contract costs with the CROs only and does not include other related costs, e.g. the manufacturing of the drug. The Company has filed an amendment to the original Phase 3 protocol for it head and neck cancer study with the FDA to allow for this expansion in patient enrollment. Should the FDA allow the amended protocol filed with them to proceed, the remaining cost of the Phase 3 clinical trial will be higher.

https://www.sec.gov/Archives/edgar/data/1301501/000119312514020548/d623715dex107h.htm
EX-10.7H 26 d623715dex107h.htm
EX-10.7H
January 24, 2017
ACHAOGEN, INC
CONTINUATION SHEET

Option Period 2: Stage 2 Non-clinical studies, Phase 3 Clinical Study.
Obligated Amount: $60,410,398.00

https://www.sec.gov/Archives/edgar/data/1638287/000110465917016633/a17-7290_4ex99d1.htm
EX-99.1 2 a17-7290_4ex99d1.htm EX-99.1
Exhibit 99.1
March 15, 2017
Gemphire

Gemphire Announces Fiscal Year 2016 Financial Results and Provides Corporate Update
In March 2017, we closed on a **$12.5 million private placement that provides funding for the AZURE-1 Phase 2 trial investigating gemcabene in NASH patients, manufacturing activities, and general corporate purposes**. This extends the Company's cash runway until at least late 2018.

https://www.sec.gov/Archives/edgar/data/1680048/000114420417017831/v462107_10k.htm
10-K 1 v462107_10k.htm
FORM 10-K
March 30, 2017
Mustang Bio, Inc

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete that development phase for our product candidates. For a description of the risk factors that could significantly affect our ability to meet these cost and time estimates, see Item 1A of this Form 10-K.

Product	Target Indication	Development Stage	Estimated time to complete phase	Estimated cost to complete phase
IL13Ra2-CAR- T	Glioblastoma	Phase 1/2	First half 2018	$2.5-5 Million
CD123 CAR-T	AML	Phase 1/2	Second half 2018	$2.5-5 Million

https://www.sec.gov/Archives/edgar/data/1624658/000119312518155283/d570609dex991.htm
EX-99.1 2 d570609dex991.htm EX-99.1
May 8, 2018
Allena Pharmaceuticals, Inc.
Allena Pharmaceuticals Reports First Quarter 2018 Financial Results and Provides Business Update

R&D Expenses: R&D expenses were $5.9 million for the first quarter of 2018 as compared to $4.4 million for the first quarter of 2017. **The increase was primarily due to costs incurred for URIROX-1 and Study 206, which were initiated during the first quarter of 2018**, as well as manufacturing costs for engineering and clinical batch production to support Allena's planned Phase 3 program. R&D expenses for the first quarter of 2017 included close-out related costs for Allena's Study 713 and Study 204.

https://www.sec.gov/Archives/edgar/data/1579428/000110465917031163/a17-12769_1ex99d1.htm
EX-99.1 2 a17-12769_1ex99d1.htm
EX-99.1
May 09, 2017
Axsome Therapeutics, Inc.
Axsome Therapeutics Reports First Quarter 2017 Financial Results

Research and development (R&D) expenses: **R&D expenses were $6.0 million for the quarter ended March 31, 2017 compared to $4.5 million for the comparable period in 2016. The increase in R&D expenses was primarily due to the conduct of the CREATE-1, STRIDE-1, and COAST-1 Phase 3 clinical trials,** as well as product candidate manufacturing costs.

https://www.sec.gov/Archives/edgar/data/1579428/000110465917031163/a17-12769_1ex99d1.htm
EX-99.1 2 a17-12769_1ex99d1.htm
EX-99.1
May 09, 2017 (Globe Newswire)
Axsome Therapeutics, Inc.
Axsome Therapeutics Reports First Quarter 2017 Financial Results

Research and development (R&D) expenses: R&D expenses were $6.0 million for the quarter ended March 31, 2017 compared to $4.5 million for the comparable period in 2016. **The increase in R&D expenses was primarily due to the conduct of the CREATE-1, STRIDE-1, and COAST-1 Phase 3 clinical trials**, as well as product candidate manufacturing costs.

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EX-99.1 2 ex99-1.htm EXHIBIT 99.1
Exhibit 99.1
August 7, 2017
GeoVax
GeoVax Reports 2017 Second Quarter Financial Results and Provides Corporate Update

During 2017, GeoVax continued its work under a **NIAID contract of up to $7.8 million for production of the DNA component of GOVX-B11 intended for later-stage clinical trials**. The Company also continued work under two SBIR grants from NIAID for both its clade B HIV vaccine, and for its vaccine for the clade C HIV subtype prevalent in Africa.

https://www.sec.gov/Archives/edgar/data/1626971/000117184317006576/exh_991.htm
EX-99.1 2 exh_991.htm PRESS RELEASE
EXHIBIT 99.1
Nov. 02, 2017
Corvus Pharmaceuticals, Inc.
Corvus Pharmaceuticals Reports Third Quarter 2017 Financial Results and Clinical Program Update

Research and development expenses for the three months ended September 30, 2017, totaled $10.7 million compared to $7.7 million for the same period in 2016. **The increase of $3.0**

million was primarily due to an increase of $2.8 million in outside clinical trial costs associated with the Phase 1/1b clinical trial for CPI-444.

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EX-99.1 2 ex-99d1.htm EX-99.1
Exhibit 99.1
May 9, 2018
Endocyte, Inc
Endocyte Provides First Quarter 2018 Financial Results and Operational Update

Research and development expenses were $5.3 million for the first quarter of 2018, compared to $8.0 million for the same period in 2017. The decrease was primarily attributable to a strategic portfolio review announced in June 2017 which led to a reduction in workforce and the discontinuation of certain research and development activities, including: **a decrease of $1.4 million in expenses related to pre-clinical work and general research, including the development of EC2629**; a decrease of $0.8 million in EC1169 trial expenses; a decrease of $0.6 million in EC1456 trial expenses; a decrease of $0.5 million in compensation expense as a result of employee terminations since March 31, 2017, and a decrease of $0.4 million in manufacturing expense for EC1169 and EC1456. These decreases were partially offset by: an increase of $0.8 million in expenses related to development of PSMA-617; and an increase of $0.2 million related to our CAR T-cell therapy program.

https://www.sec.gov/Archives/edgar/data/1630212/000161577418011426/s113520_8k.htm
8-K 1 s113520_8k.htm 8-K
FORM 8-K
October 23, 2018
Avalon GloboCare Corp

On October 23, 2018, Avactis Biosciences, Inc. (“Avactis”), a wholly-owned subsidiary of Avalon GloboCare Corp. (the “Company”), and Arbele Limited (“Arbele”) for the establishment of AVAR BioTherapeutics (China) Co. Ltd. (“AVAR”), a Sino-foreign equity joint venture, pursuant to an Equity Joint Venture Agreement (the “AVAR Agreement”), which will be owned 60% by Avactis and 40% by Arbele. **The purpose and business scope of the Joint Venture is to research, develop, produce, sell, distribute and generally commercialize CAR-T/CAR-NK/TCR-T/universal cellular immunotherapy in China. Avactis is required to contribute USD $10 million (or equivalent in RMB) in cash and/or services, which shall be contributed in tranches based on milestones to be determined jointly by AVAR and Avactis in writing subject to Avactis’ cash reserves**. Within 30 days, Arbele shall make contribution of USD $6.66 million in the form of entering into a License Agreement with AVAR granting AVAR with an exclusive right and license in China to its technology and intellectual property pertaining to CAR-T/CAR-NK/TCR-T/universal cellular immunotherapy technology and any additional technology developed in the future with terms and conditions to be mutually agreed upon Avactis and AVAR and services.

https://www.sec.gov/Archives/edgar/data/1372299/000119312518321813/d649260dex991.htm
EX-99.1 2 d649260dex991.htm
EX-99.1
November 8, 2018
Histogenics Corporation
HISTOGENICS CORPORATION ANNOUNCES THIRD QUARTER 2018 FINANCIAL AND OPERATING RESULTS

Research and development expenses were $4.6 million in the third quarter of 2018, compared to $3.5 million in the third quarter of 2017. The increase was primarily due to increases in consulting and compensation related expenses in connection with the preparation and evaluation of the data from the NeoCart Phase 3 clinical trial and the potential submission of a BLA for NeoCart with the FDA. General and administrative expenses were $2.4 million in the third quarter of 2018, compared to $2.2 million in the third quarter of 2017. The increase was primarily due to higher salaries and consulting expenses related to increased activities to support the potential commercialization of NeoCart.

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EX-99.1 2 d633511dex991.htm
EX-99.1
November 8, 2018
Spero Therapeutics, Inc.
Spero Therapeutics Announces Third Quarter 2018 Financial Results and Pipeline Overview

Following a scheduled pre-Phase 3 meeting with the U.S. Food and Drug Administration in the fourth quarter of 2018, Spero expects to submit an investigational new drug application (IND) and initiate a pivotal Phase 3 clinical trial of SPR994 for the treatment of cUTI around year-end 2018. **To support clinical development of SPR994, in July 2018 the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Threat Reduction Agency (DTRA) awarded the Company up to $54 million in non-dilutive funding and support over a five-year period.**

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November 13, 2017
Synlogic, Inc.
Synlogic Reports Third Quarter 2017 Financial Results and Recent Progress

Research and development expenses were $9.0 million for the three months ended September 30, 2017 compared to $4.1 million in the corresponding period in 2016. **The increase was**

primarily due to an increase in external costs associated with our Phase 1 clinical trial, preclinical studies, formulation development and consulting fees as well as increased internal research costs and increased compensation-related expenses associated with increased headcount.

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EX-99.1 2 exh_991.htm PRESS RELEASE
EXHIBIT 99.1
February 05, 2018
Pain Therapeutics
Pain Therapeutics Reports 2017 Financial Results and Corporate Update

Throughout 2017, we announced that the National Institutes of Health (NIH) had awarded us research grants following a competitive, peer-reviewed evaluation of our technology for scientific and technical merit. Research awards included a grant to develop a simple blood-test to detect Alzheimer's disease; a grant to study PTI-125, our clinical drug candidate to treat Alzheimer's disease; and a grant to further develop FENROCK, an abuse-deterrent transdermal patch.

We received **$1.4 million in research grant funding in the year ended December 31, 2017 from the National Institutes of Health (NIH)** that we recorded as a reduction to our research and development expenses.

PTI-125 – Proprietary small molecule drug for the treatment of Alzheimer's disease. **Phase I clinical-stage program, substantially funded by a research grant award from the National Institutes of Health (NIH)**.

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Exhibit 99.1
February 21, 2018
Blueprint Medicines
Blueprint Medicines Reports Fourth Quarter and Full Year 2017 Financial Results

R&D Expenses: Research and development expenses were $43.6 million for the fourth quarter of 2017 and $144.7 million for the year ended December 31, 2017, as compared to $24.1 million for the fourth quarter of 2016 and $81.1 million for the year ended December 31, 2016. This **increase was primarily attributable to increased clinical and manufacturing expenses associated with advancing avapritinib, BLU-554, and BLU-667 further through Phase 1 clinical trials and increased personnel-related expenses**. Research and development expenses included $1.9 million in stock-based compensation expenses for the fourth quarter of 2017 and $6.3 million in stock-based compensation expenses for the year ended December 31, 2017.

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EX-99.1 2 a18-7861_1ex99d1.htm EX-99.1
Exhibit 99.1
March 6, 2018
BIOHAVEN PHARMACEUTICALS
BIOHAVEN PHARMACEUTICALS REPORTS FOURTH QUARTER AND FULL YEAR 2017 FINANCIAL AND BUSINESS RESULTS

The increase in direct program costs reflects continued investment in clinical development and product supply. **Development costs related to rimegepant increased $23.0 million in support of two Phase 3 clinical trials, a long-term safety study, drug supply and a development milestone paid to Bristol-Myers Squibb.** BHV-3500 program spending increased $5.7 million related to formulation development and toxicology efforts, while BHV-0223 program development increased $3.6 million to advance a bioequivalence study.

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EX-99.1 2 mrns-20180306ex991a538cd.htm
EX-99.1
March 6, 2018
Marinus Pharmaceuticals, Inc.
MARINUS PHARMACEUTICALS PROVIDES BUSINESS UPDATE AND 2017 FINANCIAL RESULTS

Additionally, we sold $0.4 million in state research and development tax credits which we used to offset research and development expenses. **The decrease was partially offset by an increase of $2.3 million associated with our IV programs in PPD, for which a Phase 2 clinical trial was initiated in June 2017.**

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Exhibit 99.1
May 31, 2018
Evelo Biosciences
Evelo Biosciences Reports First Quarter 2018 Financial Results and Recent Business Highlights

The increase of $3.3 million was due primarily to an increase of $1.6 million in costs for Evelo's inflammation programs, driven by external preclinical research, manufacturing costs and licensing expense, an increase of $1.3 million in gut-body network platform expenses in line with Evelo's strategy to maximize the potential of its platform and an increase of $0.8 million in personnel costs, including increases in salaries and bonuses of $0.5 million and an increase of $0.2 million in stock-based compensation expense. Oncology and other

program expenses decreased slightly due to the timing of activities supporting the expected start of Evelo's clinical trial with EDP1503 in the second half of 2018.

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August 9, 2018
Spero Therapeutics, Inc.
Spero Therapeutics Announces Second Quarter 2018 Financial Results and Pipeline Overview

Revenue from government awards totaled $463,000 for the second quarter of 2018, higher than second quarter 2017 awards of $249,000, and were comprised of reimbursement for SPR741, SPR206 and SPR720 program expenses. **Research and development expenses were $7.4 million for the second quarter of 2018, largely in line with second quarter of 2017 expenses of $7.5 million, with spending primarily attributed to the SPR994 and SPR206 development programs**. General and administrative expenses were $3.1 million for the second quarter of 2018, generally in line with second quarter of 2017 expenses of $3.0 million with increased headcount and personnel related costs offset by lower professional and consultant fees.

As of June 30, 2018, the Company's cash, cash equivalents and marketable securities totaled $66.6 million. In early July, Spero completed a follow-on offering in which it issued 3,780,000 shares of common stock at a price of $12.50 per share, and 2,220 shares of Series A Convertible Preferred Stock at a price of $12,500 per share, for net proceeds before expenses of $70.5 million after deducting underwriting discounts and commissions. **Spero believes that its existing cash, cash equivalents and marketable securities, together with the proceeds from the follow-on offering and initial committed funding of $15.7 million under the BARDA award, will fund operations into the second half of 2020, including through top-line data readout of the planned pivotal Phase 3 clinical trial of SPR994.** A portion of the funding from our BARDA award is scheduled to support the development of SPR994 beyond 2020, provided we achieve the specified milestones and BARDA exercises all of its options under the agreement.

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Exhibit 99.1
August 21, 2018
CytoSorbents Corporation
CytoSorbents Awarded up to $3M in SBIR Phase IIB Bridge Funding by NIH/NHLBI to Accelerate U.S. Approval and Commercialization of the HemoDefend™ Blood Transfusion Filter

CytoSorbents Corporation (NASDAQ:CTSO) a critical care immunotherapy leader specializing in blood purification, announced today that the National Heart, Lung, and Blood Institute

(NHLBI), a division of the National Institutes of Health (NIH), **has awarded the company a three-year Phase IIB Bridge SBIR (Small Business Innovation Research) award, valued at up to $3 million**, to facilitate and accelerate the commercialization of its HemoDefend™ red blood cell (RBC) transfusion filter.

Dr. Phillip Chan, Chief Executive Officer stated, “The HemoDefend-RBC filter development has been generously **supported by NHLBI and U.S. Special Operations Command (USSOCOM) with approximately $1.7 million in non-dilutive SBIR Phase I and II funding**. In this next phase, NHLBI will match company funds dollar-for-dollar up to approximately $1 million each year for three years, for total funding of approximately $3 million, subject to the availability of funds and satisfactory progress of the project. This funding will be used to help finance the costs of the HemoDefend pRBC pivotal clinical trial that is expected to begin in Q1 2019 and support U.S. FDA regulatory approval, as well as initial commercialization activities including manufacturing scale-up. We thank NHLBI for their continued support.”

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Exhibit 99.1
November 6, 2018
Iovance Biotherapeutics
Iovance Biotherapeutics Reports Third Quarter 2018 Financial Results and Provides Corporate Update

The increase was primarily attributable to a $4.8 million increase in clinical trial costs due to; higher patient enrollment and an increase in the number of sites in the clinical trial of lifileucel for the treatment of metastatic melanoma, increased enrollment in the cervical and head and neck LN-145 clinical trials and the initiation of clinical trials in 2018 for new indications.

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Exhibit 99.1
Jan. 7, 2019
Ziopharm Oncology
Ziopharm Oncology Posts Letter to Stockholders

As of October 2018, we have a simplified relationship with Intrexon, with exclusive rights for the assets we desired most, and we eliminated $157 million of preferred stock held by Intrexon. The new license agreement helped pave the way for us to raise $50 million in a private placement from existing investors, secure a clinical collaboration with Regeneron Pharmaceuticals for Controlled IL-12 and announce **a joint venture with committed funding of up to $35 million to bring our Sleeping Beauty platform for CD19-specific CAR-T to China**.

Using our **Sleeping Beauty platform, we believe we can solve ongoing commercialization hurdles by manufacturing CAR-T** faster and at a fraction of the expense compared to viral vectors, thereby dramatically expanding patient access. We have made considerable progress in achieving T-cell viability needed to obtain regulatory clearance for our clinical trial. We plan to begin using this approach to treat patients at MD Anderson in the second half of 2019 with CD19-specific CAR-T therapies (with mbIL15 and a kill switch) manufactured in two days or less following gene transfer. Also, our new joint venture, **Eden BioCell, will appropriate the same Sleeping Beauty platform to undertake very rapid manufacturing in the Greater China markets to help solve production issues of CD19 CAR-T cell therapy**. We own **50 percent** of Eden BioCell with our partner, TriArm Therapeutics, **which committed up to $35 million to this joint venture**. TriArm was formed by Panacea Venture Healthcare, a fund co-founded and managed by James Huang, Managing Partner of Kleiner Perkins Caufield & Byers China (KPCB China). As our CAR-T efforts are now well funded both at MD Anderson and Eden BioCell, there is considerable upside for our investors in this program with minimal impact to our bottom-line.

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EX-99.1 2 jnce12312018exhibit991.htm
EXHIBIT 99.1
March 6, 2019
Jounce Therapeutics, Inc.
Jounce Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

The decrease in R&D expenses for the fourth quarter of 2018 was primarily due to $2.8 million of decreased external research and development costs, offset by **$1.7 million of increased external clinical and regulatory costs associated with vopratelimab as well as the initiation of the JTX-4014 Phase 1 clinical trial during the fourth quarter of 2018**.

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Exhibit 99.1
March 14, 2019
Deciphera Pharmaceuticals
Deciphera Pharmaceuticals, Inc. Announces Fourth Quarter and Year-end 2018 Financial Results

R&D Expenses: Research and development expenses for the fourth quarter of 2018 were $27.4 million, compared to $15.7 million for the same period in 2017. The increase was primarily due to an increase in **spending on the ripretinib (DCC-2618) program of $5.8 million as a result of clinical trial start-up activities related to the Phase 3 INTRIGUE study in second-line GIST**, which the Company initiated in December 2018. Expenses related to the rebastinib program **increased $1.8 million, primarily due to the Phase 1b/2 study of rebastinib in combination with paclitaxel**, which the Company initiated in October 2018, and start-up

activities related to the second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which the Company initiated in January 2019.

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EX-99.1 2 exhibit991_earningsrelease.htm
EXHIBIT 99.1
March 15, 2019
Selecta Biosciences, Inc.
Selecta Biosciences Announces Fourth Quarter and Year End 2018
Financial Results and Provides Corporate Update

Research and Development Expenses: Research and development expenses for the fourth quarter of 2018 were **$10.3 million, which compares with $13.6 million** for the fourth quarter of 2017. **The decrease was driven by reduced expenditures for our preclinical product candidates combined with the winding down of the Phase 2 clinical trial of SEL-212 in the second half of 2018**.

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EXHIBIT 99.1
28 March 2019
InflaRx
InflaRx Full Year 2018 Financial & Operating Results

This increase is primarily attributable to a **€7.1 million increase in CRO and CMO expenses for IFX-1 in connection with preparation to commence the clinical trial Phase IIb in patients with HS and the Phase II clinical program in patients with AAV**, as well as with the ongoing manufacturing activities for clinical trial material for these clinical trials with IFRX-1 and to a €3.4 million increase in employee-related costs associated with salaries, bonus, benefits and non-cash share-based compensation.

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EX-99.1 2 f6k042219ex99-1_biondvax.htm
PRESS RELEASE
April 22, 2019
BiondVax Pharmaceuticals Ltd.
European Investment Bank (EIB) extends financing agreement to €24 million total in support of BiondVax's universal flu vaccine ongoing pivotal Phase 3 clinical trial

BiondVax Pharmaceuticals Ltd. (Nasdaq: BVXV), announced today that the Management Committee of the European Investment Bank (EIB) agreed to extend the **2017 financing agreement with BiondVax by an additional €4 million**. The funds will be used in support of the ongoing pivotal, clinical efficacy, **Phase 3 trial of BiondVax's M-001** Universal Flu Vaccine candidate in Europe.

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EX-99.1 2 ex991mrtx_q12019earningsre.htm EXHIBIT 99.1
Exhibit 99.1
April 29, 2019
Mirati Therapeutics, Inc
MIRATI THERAPEUTICS REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS

Research and development expenses for the first quarter of 2019 were $34.2 million, compared to $19.7 million for the same period in 2018. The increase in research and development expenses is due to an increase in expense associated with sitravatinib and MRTX849, as well as an increase in salaries and related expense, including an increase in share-based compensation expense. **The increase in sitravatinib expense is due to increased costs to support the expansion of existing and new clinical trials, and the increase in MRTX849 expense relates to the Phase 1 clinical trial, which was initiated in the first quarter of 2019**. The Company recognized research and development-related share-based compensation expense of $5.2 million during the first quarter of 2019, compared to $1.5 million for the same period in 2018.

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EX-99.1
May 8, 2019
Arvinas
Arvinas Reports First Quarter Financial Results and Provides Corporate Update

Research and development expenses were $14.2 million for the quarter ended March 31, 2019, as compared to $7.1 million for the quarter ended March 31, 2018. **The increase in research and development expenses for the quarter primarily related to expenses associated with the initiation of our Phase 1 clinical trial of ARV-110 and IND-enabling expenses associated with ARV-471** as well as increased personnel and other expenses related to our platform research and exploratory programs research.

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EX-99.1 2 a19-9691_1ex99d1.htm EX-99.1

Exhibit 99.1
May 9, 2019
Axsome Therapeutics
Axsome Therapeutics Reports First Quarter 2019 Financial Results and Provides Business Update

Research and development (R&D) expenses: R&D expenses were $7.6 million for the quarter ended March 31, 2019 and $4.8 million for the comparable period in 2018. **The increase was primarily due to the initiation and rapid progress of the MOMENTUM study, progress of our STRIDE-1, ADVANCE-1 and smoking cessation studies**, and manufacturing costs related to our AXS-07 product candidate, which was partially offset by a reduction in the costs of previously completed clinical trials and nonclinical work.